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This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53(c).

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Additional inventors are being named on the page 2 *separately numbered sheets attached hereto*

TITLE OF THE INVENTION (500 characters max)

LIFE SIGN DETECTION AND HEALTH STATE ASSESSMENT SYSTEM

Direct all correspondence to: **CORRESPONDENCE ADDRESS**

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ENCLOSED APPLICATION PARTS *(check all that apply)*

☑ Specification *Number of Pages* 55 ☐ CD(s), Number

☑ Drawing(s) *Number of Sheets* 20 ☐ Other (specify)

☐ Application Date Sheet. See 37 CFR 1.76

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☐ Applicant claims small entity status. See 37 CFR 1.27.

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Respectfully submitted,

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Date November 4, 2003

REGISTRATION NO. 27,673 *(if appropriate)*

Docket Number: 4742/002

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Docket Number 4742/002

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November 4, 2003

VIA EXPRESS MAIL EV 225388989

Mail Stop Provisional Application
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Re: New United States Provisional Application
Inventors: Wollowitz, et al
For: LIFE SIGN DETECTION AND HEALTH STATE ASSESSMENT SYSTEM
Our Ref: 4742/002

Dear Sir or Madam:

Enclosed for filing is a Provisional Patent Application with 55 pages of specifications and 20 pages of drawings. Also, enclosed is a Credit Card Payment Form in the amount of $80.00 to cover the provisional filing fee and a Return Receipt Postcard.

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LIFE SIGN DETECTION AND HEALTH STATE ASSESSMENT SYSTEM

Field of the Invention

This invention relates to compact wearable systems for measuring a subjects vital signs, such as heart rate, respiration rate, temperature, position and motion, processing those measurements and transmitting the results of the processing wirelessly for remote monitoring. It also relates to specific sensor transducers and processing algorithms for generating electrical signals indicating vital signs, and more generally for developing diagnostic information from groups of sensor readings.

Background of the Invention

Electronic devices for monitoring a patient's vital signs at bedside are in common use in hospitals. Typically these measure, display and transmit to nursing stations EKG traces, blood pressure values, body temperature values, respiration rates and other vitals. To accomplish this, sensors such as EKG pads, pressure cuffs, thermometers, etc. are attached to the patient by multiple leads. Each of the different devices is designed for use on an immobilized patient in a stable environment. In addition there are monitoring devices for heart rate, respiration and body temperature, designed for use by athletes, pilots, astronauts, etc. Some of the systems employ wireless transmission to a monitor. Again these devices are designed for use in predictable environmental situations often where low cost and low transmission bandwidth are not limiting factors. These devices for the most part report detailed data such as full EKG trace details, although some have alarm functions if certain parameters are exceeded.

There has long been desired a reliable, reasonably low cost system for monitoring and aiding in the triaging of wounded soldiers in a battlefield environment, or triaging multiple trauma victims at an accident site. In particular there do not exist devices that could be worn by a soldier in the chaotic battlefield environment to provide enough useful information on vitals to say with confidence that the soldier is beyond the point where medical intervention would be useful, so as to be able to terminate rescue attempts that place a rescuer's life in jeopardy. Thus medics and other rescue personnel have been killed or seriously injured attempting to rescue soldiers where rescue was already hopeless. Despite the great need for systems to avoid such unnecessary casualties there has heretofore been no satisfactory system economical enough to provide to large numbers of armed forces..

Such a system would also obviously be useful in non-military chaotic situations. For example ambulances and emergency vehicles are often equipped with diagnostic equipment that can be overwhelmed in situations where there are several injured to treat simultaneously. Again, there is not available at reasonable cost health assessment systems that could be applied to multiple subjects to allow triaging to take place rapidly by persons remote from the scene of injury.

Suggestions have been made as to how such systems should be organized and what should be measured. Nevertheless, despite these suggestions and the great need, the prior art has not advanced to the point where such systems have been built and made practical.

One of the parameters recognized as important is respiration rate. However, there are significant limitations in the respiration sensors disclosed in the prior art. Typical

"respiration effort" devices employing piezo and conductive rubber sensors are manufactured by Pro-Tech of Mukilteo, Washington. A device for monitoring respiration uses an air-filled bladder and pressure sensor is described in US patent 5,611,349.

There are a number of existing devices that are generally known as "respiratory effort sensors" and which typically consist of an elastic belt that is wrapped around the chest or abdomen. A sensor is incorporated into the belt. Most commonly this is an element of flexible piezo-electric material that produces a electrical charge output that varies as the belt is stretched. Another type of belt employs a strip of conductive rubber embedded in the belt. Stretching of the belt causes the conductive strip to elongate and to become reduced in cross section, thus increasing its electrical resistance. There are a number of deficiencies in these types of devices: The piezo element is only moderately expensive, but it requires means for making electrical connections, attachment to a flexible belt, and pre-setting with a correct amount of flexure to operate properly. These all add to the cost of the application. The piezo element provides a very small electrical charge output. With output filters typically built in to the devices this appears as a high-impedance output with a range of approximately 500 microvolts peak to peak. A high-gain, high-impedance amplifier is required to boost the signal to a usable level. This adds additional cost to the application and may cause susceptibility to electrical noise interference. The piezo element, because it produces a charge output, cannot produce a true fixed voltage output. A step change in belt tension will produce an immediate change in voltage output, but this voltage will decay due to the finite impedance of the amplifier and the piezo element itself. Typically the decay time constant is on the order of 5 seconds, so it is difficult to accurately reproduce a waveform with a frequency of less than 0.2 Hz. Breathing as slow as 0.04 Hz cannot be accurately recorded. Conversely, the piezo element produces a large output signal at high frequencies and requires extensive filtering to remove extraneous high frequency components from the signal. Further, the piezo element can produce voltages in the range of 100V if subjected to shock loads or mishandling and so requires additional mechanical or electrical elements to prevent potential damage to the amplifier circuit.

The rubber strip type of sensor can produce a fixed voltage output, but is also has a very low output level because the amount of elongation during breathing is a very small fraction of the overall length. The rubber strip is incorporate into a significant fraction of the overall belt length. This is an advantage for a particular application; a more reliable signal is obtained from a heavy, prone subject during sleep studies. However, it has the disadvantage that the belt must be specially constructed for, and be an integral part of the application. The belt cannot easily be detachable or be an ordinary commercial component.

Other types of respiration sensors do not appear to be well suited for the types of applications described above. Sensors that are placed adjacent to the mouth and nose and which measure air velocity or oxygen and carbon dioxide content are obtrusive, expensive, and generally impractical for field applications. Other sensors have been developed that appear to measure mechanical impedance or muscle tension in the abdominal wall. These sensors require a strap or other device to maintain a fixed compression against the abdomen. The sensitivity of this type of device is lower than that of a device that measures the belt tension directly. Further, the device is highly sensitive

any externally applied compression such as may occur if the subject is reclining or carrying an object so that it presses against the abdomen.

Other sensors have been developed that employ a flexible tube or bladder filled with a gas or liquid. The tube or bladder undergoes changes in its internal pressure due to expansion and contraction of the chest wall. A pressure sensor is used to measure this change. The deficiencies of this type of device are several. The pressure sensor adds significant cost. The devices are highly sensitive to external compression as described above. The tube type of element in particular requires a specialized construction of a belt or strap, rather than allowing the use of ordinary elastic materials.

The present invention employs a flex sensor, i.e. a structure that varies its electrical resistance as it is flexed in response to motion of the abdomen during breathing. Known flex sensors are sensitive to bending in only one direction. They tend to be imprecise because they employ resistive material distributed along the length of the flexible element, which can bend or twist at any point. They are capable of measuring rotational motion but not force or torque loads and cannot directly sense linear motion or loads.

Prior patents that may relate to the problems of health state assessment are the following:

Respiration Effort Sensors

U.S. patent 5,513,646 entitled "Personal Security Monitoring System and Method" discloses a breath detector and a signal processor where the signal processor distinguishes between the user's normal breathing patterns and other patterns that trigger alarms.

U.S. patent 5,611,349 entitled "Respiration Monitor with Simplified Breath Detector" discloses a pneumatic breath detector using a low pass filter to reduce signals not indicative of respiration.

U.S. patent 6,377,185 entitled "Apparatus and Method for Reducing Power Consumption in Physiological Condition Monitors" discloses using a high power mode when data is written and a low power mode when inactive. Incoming data is placed in a low power buffer and transferred in a single data transfer.

U.S. patent 5,301,678 entitled "Stretchable Band-Type Transducer Particularly Suited for Use with Respiration Monitoring Apparatus" discloses a stretchable band with a conductor to wrap around a subject's torso for use with respiration monitoring apparatus.

U.S. patent 5,331,968 entitled "Inductive Plethysmographic Transducers and Electronic Circuitry Therefor" discloses such a device where the circuitry is located remotely rather than on a transducer.

U.S. patent application 2002/0032386 entitled "Systems and Methods for Ambulatory Monitoring of Physiological Signs" discloses monitoring apparel with attached sensors for pulmonary and cardiac function by including ECG leads and a plethysmographic sensor. Data from the sensors is stored in a computer readable medium for later use by health care providers.

Sensors and Signal Processors for Extracting a Physiological Measurement, Especially in a High Noise or High Motion Environment

U.S. patent 6,520,918 entitled "Method and Device for Measuring Systolic and Diastolic Blood Pressure and Heart Rate in an Environment with Extreme Levels of

Noise and Vibrations" discloses using an acoustic senor on the patient near an artery and a second acoustic transducer away from the artery. The signal of the first sensor is processed using an adaptive interfere canceller algorithm with the signal of the second acoustic sensor as interferer.

U.S. patent 6,629,937 entitled "System for Processing Audio, Video and Other Data for Medical Diagnosis and Other Applications" discloses a system for storing acoustic date in a file associated with a patient's medical record, which are analyzed to determine physiologically significant features useful in medical diagnosis based on an automatic analysis.

U.S. patent 5,853,005 entitled "Acoustic Monitoring System" discloses a transducer that monitors acoustic signals representative of heartbeat or breathing and transferred into a fluid. A comparison is made with predetermined reference patterns.

U.S. patent 6,616,613 entitled "Physiological Signal Monitoring System" discloses a system for determining blood pressure, heart rate, temperature, respiratory rate, and arterial compliance on the basis of signal characteristics of the systolic wave pulse. The systolic reflected wave pulse contour is subtracted from the digital volume pulse contour.

U.S. Patent 6,200,270 entitled "Sensor for Non-Invasive and Continuous Determination of the Duration of Arterial Pulse Waves" discloses two spaced apart piezoelectric pressure sensors along the artery.

Wireless Networks – Low Power Digital Data Networks in the "Body Area" or "Personal Area" Space; Selectable Data Rates, Data Buffering and Store and Forward Means

U.S. patent 6,577,893 entitled "Wireless Medical Diagnosis and Monitoring Equipment" discloses wireless electrodes attached to the surface of the skin of a patient and having a digital transmitting and receiving unit.

U.S. patent 5,755,230 entitled "Wireless EEG System for Effective Auditory Evoked Response" discloses an electrode array for attachment to a person that senses voltages produced by brain electrical activity. An operator interface records a verbal stimulus and provides a comparison of the brain activity with the stimulus.

U.S. patent 6,167,258 entitled "Programmable Wireless Data Acquisition System" discloses such a data collecting system where a transmitting device can receive multiple inputs and transmit a signal encoded with data corresponding to the inputs.

U.S. patent 6,223,061 entitled "Apparatus for Low Power Radio Communications" discloses such a system controlled frequency modulation where a phase lock loop synthesizer is set to an open loop state to allow FM unimpeded by the normal frequency correcting action of the synthesizer.

U.S. patent application 2002/0091785 entitled "Intelligent Data Network" provides two-way communication between a node and a master device by pausing to listen after each transmission.

U.S. patent 6,450,953 entitled "Portable Signal Transfer Unit" discloses a system for relaying physiological data employing a memory for buffering the signal and wirelessly transmitting it to a remote unit.

U.S. patent 6,454,708 entitled "Portable Remote Patient Telemonitoring System Using a Memory Card or Smart Card" discloses a system that records full waveform data on smart cards. The system uses cordless, disposable sensors.

Systems for Remote Monitoring of Personnel

U.S. patent 6,579,231 entitled "Personal Medical Monitoring Unit and System" discloses a portable unit worn by a patient that stores physiological data and issues medical alarm conditions via wireless communications. The unit works with a central reporting system for long term collection and storage of the subjects data and can automatically dispense chemicals.

U.S. patent application 2002/0019586 entitled "Apparatus for Monitoring Health, Wellness and Fitness" discloses two sensors coupled to a processor and a memory for storing the data, which is subsequently transmitted.

U.S. patent 6,605,038 entitled "System for Monitoring Health, Wellness and Fitness" discloses a sensor worn on the upper arm including an accelerometer, GSR sensor and heat flux sensor. A central monitoring unit generates analytical status data that is transmitted to a recipient.

U.S. patent 6,160,478 entitled "Wireless Health Monitoring System" discloses a system for remotely monitoring a person's physical activity through use of an accelerometer. It may be used to determine whether a person has fallen and the likely severity of the fall and trigger an alarm.

U.S. patent 6,611,206 entitled "Automatic System for Monitoring Independent Person Requiring Occasional Assistance" discloses monitoring independent signals and combining them into a single alarm for possible intervention by a supervisor.

U.S. patent 6,198,394 entitled "System for Remote Monitoring of Personnel" discloses sensors disposable on a soldier that communicate with a soldier unit that can process the information to ensure that it falls within acceptable ranges and communicate with remote monitors. Body surface and ambient temperature are monitored. The information may be stored and kept with the soldier to enable improved care as the soldier is moved to higher levels of care.

U.S. patent 6,433,690 entitled "Elderly Fall Monitoring Method and Device" discloses a system for recording acceleration and body position data from elderly or disabled persons. It detects health and life threatening falls and notifies nursing personnel of the need for assistance.

U.S. patent 6,416,471 entitled "Portable Remote Patient Telemonitoring System" discloses a system for transferring the full waveform ECG, full waveform respiration, skin temperature and motion data to a transfer unit worn by the patient on a belt for subsequent transfer to a monitoring base station where clinical data can be compared against given profiles.

U.S. patent 6,559,620 entitled "System and Method for Remote Monitoring Utilizing a Rechargeable Battery" discloses using such a battery in a system for remotely monitoring a person 's position by GPS satellite.

Wearable Physiological Sensor Arrays and Processing Means Therefor (Vests, Straps, Adhesive Arrays, Etc.)

U.S. patent D451,604 discloses an ornamental design for a vest having a physiological monitoring system.

U.S. patent 6,527,711 entitled "Wearable Human Physiological Data Sensors and Reporting System Therefor" discloses a series of rigid and flexible pods within which sensors and computing apparatus are housed. The system allows relative movement of the rigid sections with respect to each other.

U.S. patent D445,507 discloses an ornamental design for an electronics unit for a chest multisensor array.

U.S. patent 6,494,829 entitled "Physiological Sensor Array" discloses a system for transmitting sensor output. Respiration is detected by a bend sensor.

U.S. patent 6,385,473 entitled "Physiological Sensor Device" discloses a pair of disposable electrode sensors held by a flexible connector.

U.S. patent application 2003/0105403 entitled "Wireless ECG System" discloses a cardiac monitor for a patient that transmits signals digitally to a remote base station, which converts the signals back to analog electrical signals to be read by an ECG monitor.

U.S. patent D425,203 discloses an ornamental design for a chest multisensor array.

Sensors for Use in Physiological Monitoring (Temperature, Body Position, Blood Pressure, EKG or Heart Rated), Especially Under Exercise Conditions

U.S. patent 6,629,776 entitled "Digital Sensor for Miniature Medical Thermometer, and Body Temperature Monitor" discloses a thermometer based on a thermistor to control the period and duty cycle of a multivibrator circuit.

U.S. patent 5,168,874 entitled "Wireless Electrode Structure for Use in Patient Monitoring System" discloses a wireless patient monitoring system using a patch electrode having a micro-chip amplifier on one side of the patch electrode.

U.S. patent 5,622,180 entitled "Device for Measuring Heartbeat Rate" discloses a wrist strap with skin contact electrodes such that signals from a skin sensor are filtered and pulse shaped for display.

U.S. patent 6,117,077 entitled "Long-Term, Ambulatory Physiological Recorder" discloses and adhesively held transducer and skin electrode.

U.S. patent 5,976,083 entitled "Portable Aerobic Fitness Monitor for Walking and Running" discloses a system for calculating the fitness of a person using personal data and comparing that data to pedometer and heart rate values generated during exercise.

U.S. patent 4,566,461 entitled "Health Fitness Monitor" discloses a heart rate monitor for use in aerobic exercise that calculates a fitness parameter by monitoring heart rate as the subject paces through an exercise stress test protocol. The system emits beeps that the subject matches to its stride frequency. At the point of exhaustion the maximal oxygen uptake capacity is determined and is displayed.

U.S. patent 5,544,661 entitled "Real Time Ambulatory Patient Monitor" discloses a patient monitoring system including an ECG and a photo-plethysmograph , arrhythmia analysis apparatus and an expert system for determining if a pre-established critical parameter set has been exceeded. When alarmed the ECG waveform and trends are transmitted to a clinician.

U.S. patent 6,236,882 entitled "Noise Rejection for Monitoring ECGs" discloses a looping memory for storing triggered physiologic events (such as arrhythmias and syncopal events) with auto triggers to record the ECGs. Denial and extensible accommodation periods are introduced in the R-wave sensing registration for triggering data storage.

U.S. patent 5,464,021 entitled "Telemetric Transmitter Unit" discloses a electrodes having holes associated with a fluid channel to wet the part of the body underlying the electrode.

U.S. patent 5,743,269 entitled "Cardiotachometer" discloses a system for computing a heart rate from ECG signals and encoding the signals for transmission to avoid erroneous reception of signals generated by noise or interference.

U.S. patent 6,554,773 entitled "Method and Arrangement for Blood Pressure Measurement" discloses a pressure generator and measuring sensor to determine diastolic and systolic pressure.

U.S. patent 6,575,915 entitled "Method and Apparatus for Identifying Heartbeat" discloses measuring arterial pressure, filtering the resulting signal and deciding whether the signal represents a heartbeat.

U.S. patent 6,580,943 entitled "ECG Electrode Structure and Method for Measuring ECG Signal From a Person in Water" discloses use of two electrodes for comparison, one of which contacts only the water.

U.S. patent 6,616,612 entitled "Measuring Arrangement" discloses measuring a pressure signal from a person through a structure in contact with the body and converting it into an electrical signal.

Pressure Sensors Using Conductive Ink

U.S. patent 5,086,785 entitled "Angular Displacement Sensors" discloses a conductive ink sensor for detecting angular displacement of an object.

U.S. patent 5,652,395 entitled "Bending Sensor" discloses a pressure sensitive electroconductive ink coated on a flexible segment. The electrical resistance is reduced under pressure as when the segment is bent .

Brief Description of the Invention

A wearable platform embodied in a belt or patch provides physiological monitoring of soldiers during field operations or trauma victims at accident sites. It is referred to as the Life Signs Detection System (LSDS) since one of its functions is to determine with confidence whether a warrior is alive. The system also makes health state assessments. A single wearable package includes sensors for heart rate, body motion, respiration rate and intensity, and temperature and further contains a microprocessor and short range transmitter. A separate wearable package that would be expected to be carried by a soldier for other communication purposes contains a local transceiver hub.

The respiration sensor is a novel construction which uses conductive ink in a novel manner. A small rectangular area of the ink is coated on an arched structure so that flexing of the arch either to increase or decrease its radius of curvature modifies the resistance of the structure. This is utilized to set the unstressed resistance of the arch structure and to allow a greater range of resistance values capable of measuring distortions in different deformations of the arch. This is employed in unique respiration sensor configurations.

A feature of the invention is the integration achieved between the various components. The respiration sensor for example also gives information on motion of the subject and therefore supplements the information provided by an accelerometer sensor. And, all the sensor information is assimilated by the health state algorithm. Thus there is a synergistic relation between the various components of the sensor and processor elements..

The heart rate sensor employs skin contact electrodes and a high impedance amplifier to generate an electrical EKG signal. An analog circuit running a novel algorithm obtains the R-wave period from the EKG signal and produces electrical pulses with the period between pulses corresponding to the R-wave period. The pulses act as interrupts to a microprocessor, which uses an internal clock to determine the time between adjacent pulses.

Body motion is sensed by an accelerometer contained within the package. The accelerometer generates a pulse-width-modulated signal corresponding to acceleration along the main body axis. The microprocessor converts the pulse-width-modulated signal to a digital format and uses this as a simple measure of overall body motion. By using an accelerometer of a type that can respond to static acceleration, body orientation can also be partially determined; the static acceleration signal due to gravity will decrease to a minimum when the wearer's body is horizontal. Alternately, the accelerometer may produce an analog output or have multiple outputs corresponding to motion of multiple orthogonal axes; the microprocessor will then employ an appropriate analog-to-digital converter or multiple inputs respectively.

The respiration sensor generates an analog signal corresponding to expansion and contraction of the chest or abdomen. The analog signal is electronically filtered and then converted to a digital format by an analog-to-digital converter, which is part of the microprocessor. The signal is then digitally filtered and processed to obtain period and amplitude values.

A temperature measuring element is mounted in the wearable package adjacent to the skin of the wearer and provides a digital signal to the microprocessor. Changes in body temperature over time and relative to a baseline value may be obtained.

All data received from the sensor is processed in the microprocessor to produce a simplified, low-bandwidth output. The output is transmitted from the wearable package by a short range RF transmitter contained within the unit.

An additional component, called the Local Hub, is also worn by the subject. In its simplest form the local hub contains an RF receiver, a medium or long range RF transmitter or transceiver, and a microprocessor. The local hub receives the transmitted data from the LSDS wearable package and retransmits the signals to a remote station or base station. Retransmission is not necessarily synchronous with reception; the microprocessor may perform additional processing on the received data and may reconfigure the data for more efficient transmission.

A sensor subsystem is responsible for conversion of one or more hardware biologic indicators into a periodic digital data packet. This data packet will be transmitted over a local, low-power RF link to the hub, at an appropriate data rate.

A hub subsystem is responsible for collection of all the local sensor data, performing additional data analysis if needed, and relaying the information to the remote station. The hub subsystem is responsible for recognizing and maintaining association to a specific set of sensor subsystems, so that data from other sensors that are physically proximate, but are monitoring a different person will not get mixed in. The hub subsystem is responsible for providing periodic and/or on-demand advertisement of it's availability and status, and to accept a connection from one or more external display systems.

A remote subsystem is responsible for collecting data from up to 20 hubs, and displaying them on a normal-sized laptop or portable computer screen.

A medic PDA subsystem is responsible for providing the detailed data display for a selected hub.

The location of the medium or long range transmitter in the local hub, rather than in the LSDS wearable package, provides several important advantages. A medium or long range transmitter requires a larger battery (or other power source) and a larger antenna than a short range transmitter. The wearable LSDS package must be placed directly against the wearers skin and its position on the body is determined by the operation of its physiological sensors. To avoid discomfort and interference with physical activities it is important that the LSDS wearable package be as thin and light as possible. Conversely, the local hub with its larger battery and antenna can be placed at any convenient location in or on the wearer's clothing or gear. Also, the use of the separate local hub allows for much greater flexibility in the use of additional sensors and communication devices.

The LSDS wearable package may be extended to include additional elements that provide supplementary physiological data and other communication and information channels.

The heart rate signal input may be extended by the addition of a direct link between the EKG amplifier and an analog-to-digital converter on the microprocessor. This allows more complex EKG data to be obtained than a simple pulse rate metric.

The motion sensor is extended by the use of two orthogonal accelerometer inputs. That provides more accurate assessment of body orientation and may improve the assessment of the wearer's activity level.

The respiration sensor is extended by the addition of a second input channel, deriving two signals from the same sensing element. The amplified signal passes through low-pass and band-pass filters that are arranged in parallel; the resulting signals are independently digitized. The low-pass filtered channel, typically limited to frequencies below approximately 1 to 2 Hz, transmits mainly the respiration signal since respiration frequencies are typically in the range of 0.05 to 0.5 Hz. The band-pass filtered channel, typically limited to frequencies from approximately 2 to 8 Hz, transmits signals resulting from active use of muscles of the chest, back, and abdomen such as occur during walking, running, lifting, or using implements. This may be used an alternative means to the accelerometer for assessing motion of the wearer. Also, the band-pass filtered channel may be used to assess the likelihood that respiration or EKG signals may be corrupted by intense exertion and motion of the subject. The low-pass and band-pass filters may be external analog filters, which allows for a very low sampling rate for minimal energy consumption. Alternatively a higher sampling rate may be used and the two filters instantiated in software running on the microprocessor.

The sensor array is further extended by the addition of one or more acoustic sensors, which may be of several types. A stethoscope type or other contact type of acoustic sensor, placed on the chest, back, or neck, may be used to monitor heart or breath sounds. A high-frequency range pickup may be used to detect physical shocks or impacts. A simple microphone may be used to monitoring the wearer's voice or environmental sounds.

Additional sensors of as yet undetermined types may also be incorporated, using digital, pulse width modulated, or analog to digital inputs to the microprocessor.

The local hub may be extended in several ways. Additional sensors, instruments, or communication devices may be interfaced to the local hub using wired or wireless connections. Typically these devices would be of types that would be inappropriate to include in the LSDS wearable package due to size, weight, power consumption, placement requirements, or simple because they are unrelated to physiological monitoring. Possible additions are GPS receivers, vocal communication systems, or instruments for monitoring fluid intake. In addition, both the local (short range) and remote (medium or long range) wireless links may be made bi-directional. This will allow the local had and the LSDS wearable package to receive instruction as well as transmit data.

In one physical configuration for the LSDS wearable package, a rigid or semi-rigid center section contains the battery and electronics. Two elastomeric side extensions contain the respiration and EKG sensors. The EKG sensors are conductive pads mounted flat on the reverse side of the side extensions. The short arched section on either extension can contain a respiration sensor.

In an alternative configuration an elastomeric housing contains a flexible circuit board, battery, respiration sensor(s) and EKG electrodes. The EKG electrodes are conductive pads attached to the reverse surface of the housing. The respiration sensing elements are placed within the housing, with one end fixed to the housing and the other end fixed to a strap attachment loop that extends from the edge of the housing. The respiration sensor elements are thus protected from impact and environmental damage.

Either of the two above LSDS wearable package configuration are worn. An elastic strap connects to the two ends of the device and wraps tightly around the body. The placement of the device over the lower ribs and beneath the pectoral muscles serves several purposes. The EKG electrodes are well placed to detect the R-wave EKG signal. The lower ribs have the greatest mobility and will generally expand and contract significantly whether the wearer is breathing primarily from the chest or the diaphragm. The location below the pectoral muscles is somewhat protected and minimizes chafing or interference with normal tasks. The loop on the upper edge of the LSDS wearable package attaches to a single shoulder strap, connected to the main strap at the back, that prevents the device from slipping down during prolonged use and strenuous activity.

In another alternate configuration a strap is not employed. In this configuration the battery, electronics, respiration sensor, and temperature sensor are contained in a rigid central housing. The EKG electrodes are placed at the end of two stalk-like extensions. The back of the device may be mounted to the subject's skin with an attached sheet of flexible material coated with a medical grade adhesive. Alternately, an external fixture may hold the device in contact with the subject's skin. The respiration sensor employed here does not operate using belt tension but instead by variations in contact pressure against the abdomen during respiration. The large adhesive attachment area or external fixture provides a relatively fixed reference for the small-area respiration sensing element..

In attaching the apparatus to the subject, the EKG electrodes are placed for high R-wave sensitivity and the respiration sensor is placed over the upper central abdomen where large respiration-induced movements occur. This configuration of the LSDS

wearable package is intended for less active subjects and, in particular, use with injured or immobile subjects where use of an elastic strap around the body may be impractical and rapid application is required.

Processing of signals takes place at various levels within the electronics worn by the subject. The levels are:

1. Original Signal – The raw, unprocessed signal generated by a sensing element.
2. Preparation – Basic analog processing applied to the signal to make it usable for later processes.
3. Feature Extraction – Analog and/or digital processing of the signal to obtain recognition of basic signal features such as frequency and amplitude.
4. Scoring – Digital processing to determine metrics of extracted features such as averages, trends, and bin (level) counts.
5. Evaluation – Digital processing of data to determine overall conditions, access whether data is within normal ranges, and to generate warnings or alarms.
6. Extended Evaluation – Intensive digital processing to correlate multiple signals or multiple subjects, access the quality of received data and signals, and to perform complex feature extraction.

Certain processes may be considered "shift-able" in that they may be performed at different locations depending on specific needs. An example of a shift-able process is processing of heartbeat rate. All EKG processing is performed using a low-power analog circuit within the LSDS wearable package. A single metric of pulse rate (or pulse period) is transmitted from the wearable package to the local hub and then to the remote station, minimizing power and bandwidth requirements. In a shifted process the analog pulse detector is bypassed and the raw EKG signal is digitized at the microprocessor. The digitized EKG signal is then transmitted to the local hub and then to the remote station. At the remote station the EKG signal may be viewed and more complex feature extraction may be performed. Significantly greater power and bandwidth is required to transmit the full EKG signal.

The wireless links are preferably bi-directional so that the remote processor can send commands to the wearable package and local hub. In typical operation the simple pulse rate metric would normally be transmitted. At certain intervals, or when concerns were noted, the remote processor would send commands to place the wearable package and local hub into a higher bandwidth transmission mode and to send the raw EKG signal directly to the microprocessor in the wearable package. After a period of time the remote processor would send commands to return the devices to their normal operating mode.

The extended evaluation employs an algorithm that is capable of making a medical evaluation of subject condition and determining a confidence level for the evaluation.

It is an object of the invention to provide a unique sensor technology for the respiration sensor.

It is a further object of the invention to provide unique housings for the sensors. In addition to the novel flex sensor being incorporated into a band that encloses the subject's torso and measures respiration by the change in tension of the band, there are other embodiments where the sensor is contained in a patch that is adhered to the anatomy of the subject without the need for the band. Incorporated into either embodiment are the other sensors and the electronics to process the signals from the sensors and to transmit the signals to a local hub.

It is a still further object of the invention to provide the electronics that allows most processing to take place on the PC board including in the sensor housing. This local processing reduces the bandwidth requirements for transmission, since it is not necessary to transmit waveforms for remote analysis. In addition the electronics are designed to conserve battery power to enhance the battery lifetime.

It is yet another object of the invention to provide novel algorithms that are used to process the signals from the EKG sensors in order to isolate the R wave peaks from background noise and the respiration peaks from their background.

It is still another object of the invention to provide a health state assessment algorithm to determine physiologic state and decision confidence using a rule set based on one's personal baseline. The assessment may be limited to good/weak/bad determinations of health. The health state assessment algorithm can also provide triage indicators – to acquire, analyze and report appropriate collections of life sign parameters to support specific diagnosis assessments. The algorithm may be used to determine the medical state of the subject for transmission to a local hub and for display on a remote monitor. This algorithm is based upon medical determinations and is subject to particularization for restricted subject populations or unusual circumstances.

Other objects of the invention will be apparent from the following detailed description of the invention.

Brief Description of the Drawings

Figure 1 is a drawing of the LSDS worn by its subject.

Figure 2 is a perspective drawing of the central housing and extensions viewed from the back side.

Figure 3 is a perspective drawing of the central housing and extensions view from the front.

Figure 4 is a cut away drawing of the extension and flex sensor.

Figure 5 is a drawing of the patch embodiment of the invention worn by its subject.

Figure 6 is a drawing of a flex transducer for a bending sensor mode.

Figure 7 is a drawing of a the flex transducer for a bending sensor flexed downwards.

Figure 8 is a drawing of a the flex transducer for a bending sensor flexed upwards.

Figure 9 is a drawing of a flex sensor element.

Figure 10 is a drawing of a flex sensor mounted to a support.

Figure 11 is a drawing of a flex sensor and support.

Figure 12 is a drawing of another flex sensor and support.

Figure 13 is block diagram of the electronics of the LSDS.

Figure 14 is the circuit diagram for the on board processor and power control

Figure 15 is the circuit diagram for the ECG front end circuitry.

Figure 16 is the circuit diagram for the accelerometer and RF circuit.

Figure 17 is the circuit diagram for the respiration circuitry.

Figure 18 is a schematic representation of the power management scheme.

Figure 19 is a block diagram of the major tasks of the central task manager.

Figure 20 is a block diagram of the Heart Rate Calculation algorithm.

Figure 21 is a block diagram of the process timing.
Figure 22 is a flow chart of the ECG pulse detection interrupt circuit.
Figure 23 is a flowchart of the low pass filter and noise cancellation circuit.
Figure 24 is an example of pulses filtered for R-waves.
Figure 25 is an example of pulses analyzed for consistent inter-beat intervals.
Figure 26 is a flow chart of the trend-acquiring process.
Figure 27 is a diagrams of R-wave pulses found when tracking an existing trend.
Figure 28 is a flow chart of the trend-tracking process
Figure 29 is a chart showing the sample averaging scenario.
Figure 30 is and operational overview of the communication to a serial port.
Figure 31 is an example of a bit stream.
Figure 32 is and example of a bit stream leader with all zeroes.
Figure 33 is a diagram so show how orientation is interpreted.

Detailed Description of Preferred Embodiments of the Invention

As shown in Figure 1, the Life Signs Detection System (LSDS) is an apparatus containing a group of sensors for certain vital physical parameters of a subject person and electronics to receive and interpret electrical signals from the sensors, process the signals and transmit information on the physical status of the subject. The group of sensors and electronics is embodied in a carrier **1** arranged to be worn by the subject. The electronics residing on a PC board is designed to accomplish most signal processing at the location of the subject and to avoid the need for robust networking and centralized computing that require large amounts of bandwidth to transmit raw signals for analysis. Such large bandwidth is impractical in field settings where bandwidth is low, unreliable and localized responsiveness must be maintained.

The carrier comprises three main elements – a central housing **3**, two flexible extensions **5** containing external sensors **7** (see Figure 2), and a harness **9**. The LSDS package is intended to be worn underneath the subject's clothing with the housing positioned approximately over the solar plexus. It is held in place by an elastic harness that consists of one strap (belt) that passes around the subject's back and another that passes over the left shoulder. The two flexible extensions **5** protrude from the sides of the housing and form the connections to the horizontal strap **11** of the harness.

The harness is sewn from lengths of an elastic webbing such as Velstretch, with Velcro-type "loops" on one side and a comfortable flock-like texture on the opposite side. It is sewn so that the shoulder strap joins the horizontal strap at the center of the wearer's back. *To the free end of the shoulder strap and the two ends of the horizontal strap are sewn a short section of Velcro-type "hook" material. This allows the strap ends to be looped through rings on the housing and extensions and attached back to itself ("hooks" to "loops"), making the strap lengths and strap tension easily adjustable. The harness is always turned so that the flock-like surface is against the skin for comfort.*

The housing consists of a pair of matched polymer castings, the front and back halves forming a closed shell. The size of the housing is determined to fit a PC board containing the electronic components and a battery and the width of the harness straps. The housing is designed to be assembled using four screws. Threaded metal inserts are embedded in the back half so that the case can be repeatedly assembled and disassembled without stripping the female threads.

Several features are molded into the housing. Standoff bosses are provided to support and locate the PC board. Openings on both sides are shaped to fit the ends of the housing extensions. Elongated bosses with blind holes are used to attach the housing extensions, using either cement or pins. A loop on the top edge acts as the attachment point for the adjustable shoulder strap. A small opening on the side of this loop is sized to fit a miniature electrical jack used for recharging the internal battery.

The housing extensions are preferably fabricated as molded elastomeric components. In an alternative fabrication of the housing extensions, a covering of nylon fabric is sewn over the "loop" side of the Velstretch to cover the sensor wiring and to make the material less stretchy – approximating the stiffness of a molded elastomeric part. The inner ends of the extensions are mounted to the housing using a cyanoacrylate or other adhesive. To the outer ends of the extensions are sewn rectangular plastic loops that act as attachment points for the adjustable ends of the horizontal strap. The housing extensions act as supports for two respiration sensors and two EKG electrodes.

Respiration Sensors

Respiration sensors **13** (Figure 4) are used in connection with an electronic circuit to provide a signal indicative of body motions accompanying respiration. The two sensors may be used individually or they may be connected electrically in series and thus act to the electrical circuit and microprocessor as a single sensor. They comprise a strip of flexible film material **15** that is overprinted with conductive leads **17** connecting to a small (millimeter dimensioned) area of resistive material having the property that its resistance increases as the strip is flexed convexly. The sensor is laminated using a thermal adhesive to a thicker base layer **21**. The two are then thermoformed so that the center of the strip (containing the small resistive area) is shaped into an arch **23** while the ends **25** remain flat. *Small rectangles of fabric are mounted to the flat ends using a thermal adhesive; this provides a means for sewing the sensor securely to the housing extensions. Grommets or rivets are added to the sensor so that wires can be soldered in place to connect to the PC board.*

Each respiration sensor is sewn to the front surface of one of the housing extensions **5**, aligned along the extension. The fabric of the extension is pushed together slightly under the arched section so that the tension load when worn will be mainly across the sensor. The nylon cover material **27** is split so that the center of the sensor is uncovered, both to make it visible and to allow for greater compliance. Alternately, a flexible or rigid protective cover may be placed over the sensor. The term "compliant" is used here to mean elastically deformable or spring-like, as opposed to the extremes of either rigid or completely flexible.

Figure 1 shows the manner in which the configuration here described is worn be the subject. The complete assembly of central housing and extensions **3** is attached at both ends to an elastic strap that wraps tightly around the subject's back, holding the components tightly against the skin and placing a tensile load across the respiration sensor. An optional shoulder strap **9** prevents the assembly from slipping down during physical activity. The assembly is preferably placed in a horizontal alignment below the lower edge of the pectoral muscle **29** and crossing over the lower ribs **31**. This area undergoes a large degree of expansion and contraction during respiration and causes respective increases and decreases in the tension across the sensors, thus producing changes in resistance.

EKG Sensors

EKG sensors are pads **7** of conductive rubber wired to the electronic circuit of the LSDS contained on a PC board within the central housing **3** together with the battery.. They are sewn to the back of the housing extensions so that they will be in direct contact with the wearer's skin. A small wire (not shown) is threaded into the rubber and connected to a longer wire (or other pathway) to create an electrical connection to the PC board. The wire is attached so that it will not come into contact with the wearer's skin.

Another, more mass producible embodiment of the LSDS is similar in form, but this alternative design includes the following features:

1. *The housing extensions are fabricated from an injection molded elastomer. The respiration sensors and EKG electrodes (also molded) are embedded into the housing extensions using a combination of multi-shot molding and mold-in-place techniques. Sealing lips are molded into the ends of the housing extensions that fit into the housing.*
2. *The housing is injection molded and is assembled using either solvent bonding or ultrasonic welding rather than screws. This provides both increased strength and a water-tight seal. Contacts for the battery charger may be molded into the case.*
3. *The rear half of the case may be molded from a flexible material for greater comfort. Alternatively, a pad, cover, or coating of a soft, textured material may be applied to the outer surface of the rear half of the case.*
4. *The harness (not shown) may be formed from a elastic material that does not have the Velcro "loop" surface but does present a soft, textured surface against the skin. Velcro or other types of adjustable devices may be attached to the strap ends to make them adjustable and removable.*

Due to resilience of the straps, the EKG electrodes are able to remain in contact with the same portion of skin as the subject breathes, rather than having the electrodes slide over the skin. This significantly reduces the surface resistance where the skin and the electrode are in contact.

The Respiration Flex Sensor

The respiration sensor thus employs a novel deformation transducer element **19** that varies in electrical resistance as the chest or abdomen expands and contracts due to respiration. The respiration sensor provides relatively high signal levels that can easily be interfaced to a recording or transmitting component.

The novel transducer of the flex sensor is employed to produce an electrical resistance that varies with applied tensile, compressive, or bending loads. The basic structure consists of a flexible, variable resistance element **19** and a compliant backing or support element **21**. The resistance of the flexible element increases as its radius of curvature decreases. It has a minimum resistance value when flattened. Two such elements are arranged on the extension so that each flexible element has a preset curvature when no load is applied. A tensile load while taking a breath will tend to reduce the curvature, thus decreasing the resistance; a compression load will act oppositely. Bending loads will similarly cause the resistance to increase or decrease depending on the direction of flexure. The backing or support element acts as a spring and limits the degree

of deformation of the flexible element. This results in the change in resistance being approximately proportional to the applied load.

Respiration Tension Sensor

Various structures could be used to hold the transducer against the subject to detect respiration or other motion. The transducer means may be employed in one of several configurations. In one configuration it is employed as a tension sensor. The transducer is mounted to an elastic strap **11** such that the transducer is subjected to the full tensile load applied when the strap is stretched along its length. The strap, which is formed into a belt that fits around the chest or abdomen of the subject, is fabricated or adjusted to a length that insures that it will always be loaded in tension as the subject breaths or moves about. As the subject inhales and exhales, the tension on the strap increases or decreases correspondingly. This creates a corresponding change in the electrical resistance of the transducer as described above.

Respiration Bending Sensor

In another configuration shown in Figure 5, the transducer means is employed as a bending sensor that could be embodied in a patch **33**. As shown in Figures 6-8, the transducer is attached between two projecting arms such that the rotation of either arm relative to the other will produce a change in electrical resistance. A flexible pad or backing **37** is applied to one side of this transducer assembly. A pressure applicator **39** is provided to compress the entire assembly against the subject's abdomen, oriented so that the flexible pad is placed flat against the skin. The pressure applicator may consist of a belt or strap, an external clamp or fixture, or an adhesive pad **33** that attaches to the surrounding skin. The pressure applicator is configured such that force is applied near the proximal and distal ends of each projecting arm with approximately equal force so that the flexible pad conforms to the curvature of the skin. The pressure applicator is further configured such that the mechanical compliance of the pressing elements is greater at the proximal ends than at the distal ends of the arms. When the subject inhales the abdominal wall expands. At the proximal ends of the arms the greater compliance acts to resist this motion to a lesser degree than at the distal ends. The result is a relative rotation of the two arms and a corresponding change in resistance of the transducer means. When the subject exhales the rotation is reversed, causing an opposite change in resistance.

Additional embodiments may be generated by employing multiple transducers and multiple straps, harnesses, or pressing devices. Further, the strap or pressing devices may be fabricated as, or incorporated into, a garment, and may support additional sensors or other devices. In either embodiment, the varying electrical resistance may be converted into a voltage or current signal using a variety of electrical circuits and may be converted to a digital or modulated format for additional processing.

The flex sensor has uses beyond that of the LSDS. Accordingly it is here described in further detail. The respiration sensor employs a sensing element employing a flat, flexible polymer strip that is coated on one side with a material that increases in electrical resistance as it is flexed or bent convexly to a smaller radius of curvature. Low resistance traces are coated onto the strip to allow connection of the resistive element to an electrical circuit.

The flex sensor has a shape of the sensor element preset into a convex arc and then to attached to a compliant or spring-like support. Figure **9** shows a typical geometry for the preset shape. The flat sensor element **101** is bent into an arched shape so that the

resistive coating **102** is flexed convexly. The ends of the element are shaped to allow attachment to any two surfaces or objects that will undergo relative displacements. This may take the form of a flattened tab, as shown here, or any other appropriate geometry. The initial degree of flexure and the initial positions of the connected objects may be considered a neutral position for the purpose of explanation. The electrical resistance with this degree of flexure is thus the neutral resistance.

As one attached object is displaced away from the other **103** the arch section becomes more flattened, so the electrical resistance decreases. The displacement of one attached object toward the other **104** will increase the amount of flexure, increasing the resistance. Similarly, a rotation upward **105** or downward **106** of one attached object relative to the other will cause a respective decrease or increase in flexure and thus a respective decrease or increase in resistance.

A combined linear and rotation movement may have an additive or a canceling effect on the resistance. It is generally preferable that the connected objects either be constrained to either linear or rotational displacement alone. For the case of relative rotation between the two objects it is further preferred that the axis of rotation be positioned in relation to the sensor element so as to not result in an additional linear displacement.

The means described above allows the sensor element to sense rotational and linear displacement in a bi-directional manner. The addition of a shaped compliant support allows sensing of force and torque loads between two objects.

Figure **10** shows the sensor element mounted to a shaped compliant support **107** such that the support has an arched center section and ends shaped to attach to any two objects. The resistive portion of the sensor element is maintained in close contact with the support surface. The support acts as a spring that maintains a neutral shape, and thus a neutral resistance, unless a force or torque is applied across it.

The compliant support **107** may be shaped by a multiplicity of means. If it is made from a metal it may be stamped to shape. If made from a polymer it may be thermoformed, cast, or molded. Various other production means may be employed. In all cases the support is shaped so that the arched form is maintained in the absence of external loads or constraints.

Application of tensile force between the attached objects causes a reduction in support flexure **108** and thus reduces the electrical resistance. Application of compressive force causes an increase in support flexure **109** and thus increases the electrical resistance. Similarly, a torque upward **105** or downward **106** of one attached object relative to the other will cause a respective decrease or increase in flexure and thus a respective decrease or increase in resistance. It is generally preferred that the sensing device be mounted such that it is subjected to either force (linear) or torque (rotational) loading alone.

The compliance of the sensor and support is the relative displacement between the two mounting points per unit of applied load. It can be seen that the stiffness depends on a multiplicity of factors including the modulus and thickness of the support material and the length and curvature of the section of the support adjacent to the resistive section of the sensor element. The compliance may further be refined by shaping the support to have varying thickness or width along its length. The support may be further shaped with slots, ribs, corrugations or other features to increase or decrease its compliance.

The sensor element and support may alternately be assembled such that the sensor element is mounted to the bottom of the arched surface of the support rather than to the top of the arched surface. In this arrangement, the side of the sensor element containing the resistive element is aligned against the bottom of the arched surface of the support. ———Thus the resistive element is bent convexly as previously described. The mounting means may be mechanical or adhesive, but liquid adhesives are not preferred over the resistive material as this may interfere with its variable resistive properties. The means of operation is unchanged in that applied forces or torques will cause a deformation of the support and thus a deformation and change in resistance of the sensor element. With this arrangement, the resistive element may be better protected from environmental or impact damage.

The sensor and support are generally described herein as separate components that are assembled together. In fabrication the resistive and conductive materials are coated onto a thin plastic sheet and then treated to create the requisite properties. Typically the plastic sheet is then laminated to a stiffer backing and cut into strips. The force and torque sensor of the type shown in figure **10** may be created by plastic deformation of the laminated flat flexible sensor and backing into an arched shape. Alternately, the flexible sensor element may be applied to a support or backing that has previously been formed into an arched shape.

An alternate means for fabricating the force and torque sensor is to apply the resistive and conductive materials directly to a thicker and stiffer base that then acts as the compliant arched support. This eliminates several processing and assembly steps.

With appropriate geometry and construction the sensor and backing as described above are applied to sensing the tension in a belt or other flexible tensile element. The belt may have small a gap, fold, or pleat between the two points of attachment for the sensor element support. It is preferred that all or most of the belt tension be transmitted through the sensor support. Changes in the tension of the belt will cause corresponding changes in the electrical resistance of the sensor element.

For general use of the flex sensor, numerous types of electrical circuits may be employed to generate a useful electrical signal that varies proportionally to the change in electrical resistance. A variable voltage may be produced with a simple divider circuit or a fixed voltage may be placed across the resistance to produce a variable current. A capacitive-resistive circuit may be used to produce a variable charge or discharge time. For certain applications it may be preferable to use a decoupling circuit so that the output signal becomes proportional to the changes in resistance rather than the absolute resistance.

Figure **11** shows a simple sensor and support configuration that may be used to allow attachment to a belt or other device. A short sensor element **112** is mounted on a support **114** that has a mounting hole feature at both ends. An offset section **113** of the sensor element has conductive traces that lead to the resistive element. The assembly can thus be mechanically attached to two portion of a belt or other objects, and wires or an electrical connector can be connected to the resistive element of the sensor.

Figure **12** shows a sensor and support configuration that may be used to make a fixed connection and a temporary or adjustable connection. A short section of the sensor **115** contains the resistive element while an extended section **116** contains conductive traces and connects to conductive pins **117**. The pins may be plugged in or soldered to an

electric circuit. One end of the support **119** has a mounting hole to allow a fixed connection to a belt or to another object. The other end of the support **118** is provided with slots through which a belt can be passed to make an adjustable or temporary attachment. An adjustable attachment may be used to set the belt tension to a range that is optimal for the sensor.

Figures **1, 2, 3 and 4** show a more complex configuration that includes two sensing elements used in a respiration sensor. This configuration includes additional sensors. Two respiration sensor elements are provided for the sensor for added reliability in cases where the subject may be leaning or reclining against one sensor element.

Figures **6, 7,** and **8** show schematically the alternate means of sensing respiration using a similar sensing element but without the need for a belt around the subject. In this configuration the sensing device is pressed against the abdomen of the subject. Figure **6** shows the configuration at a neutral position. The skin and underlying tissue of the abdomen **35**, shown in section view, are pressed against by two flat extensions **37** that are connected by an arched section **41** on which a resistive sensing element is mounted in the manner previously described. Similarly, a rotation upward or downward of one attached object relative to the other will cause a respective decrease or increase in flexure and thus a respective decrease or increase in resistance. A rigid or semi-rigid backing **39** is fixed at a short distance from the skin surface. Compliant elements **43, 45** fit between the backing and the flat extensions and act to press the flat extensions against the skin. The compliant elements may be springs, foam rubber, or any other springy material. The compliant elements **45** at the proximal ends of the extension have a different degree of compliance than the compliant elements **43** near distal ends, either using different material or different geometry. In this illustration the compliant elements at the distal ends may be considered to have the greater compliance or to be rigid. The abdominal wall can be considered as an elastic surface that will deform when pressed by the flat extensions. Not shown in the illustration is a pad or separator that would typically lie between the flat extension and the skin and which would act both to protect the electrical elements from moisture and to more smoothly distribute the force applied to the skin for better comfort.

Figure **7** shows the effect on this configuration when the subject inhales. The abdominal wall expands, increasing the force against the flat extensions. Because the abdominal wall is elastic, the force will be distributed against the flat surface and balanced by deflection of the compliant elements. The more compliant elements **45** will deflect to a greater degree, causing a rotation of the flat extensions and increasing the flexure of the center section and thus the electrical resistance of the attached resistive element. Figure **8** shows the opposite effect when the subject exhales and the abdominal wall contracts. The flat extensions rotate in the opposite direction, reducing the flexure of the center section and thus decreasing the electrical resistance.

The geometry and configuration of this type of sensing element can be varied in many ways. The required factors are the application of a force against the skin, a differential compliance such that a differential motion results from expansion and contraction of the abdomen, and a resistive sensing element placed so that its degree of flexure changes as a result of the differential motion.

Figure **5** shows two preferred locations **33** for this type of respiration sensing configuration against the abdomen **47**. The configuration may be placed to the side, directly below the ribcage or across the centerline of the body.

An electronic circuit, typically comprising both analog and digital components, is provided for analysis of signals affected by the flex sensors to determine respiration rate. The circuit simply looks for high and low peaks in the input signal and determines the peak to peak (p-p) time and amplitude. The results are compared to predefined min and max cycle times and a threshold amplitude to determine the presence or absence of breathing. The cycle period, p-p amplitude (arbitrary scale), and ratio of inhalation to exhalation times are reported. The analog input is digitally filtered to remove signals above ~1Hz. A second order filter would remove "movement" signals. A secondary circuit may be applied to "score" the output signal over a longer period, perhaps 60-180 seconds, and so produce a more reliable estimate of the presence of absence of breathing. This may take the form of "minimum of X seconds of breathing detected during the previous Y seconds."

The electronic circuit reports the presence of body motion as seen as signals above 1 Hz . After applying a 2nd-order high pass filter to the analog signal, the result is rectified (absolute value). The result is compared to a reference. If it is greater than the reference an output flag is switched on and a timer is (re)initialized. The output remains on until the timer runs out – typically in 0.1-0.5 seconds. The intent is that activities such as walking will cause the output to remain on continuously. Alternatively, the rectified signal may be processed with a low-pass filter with a >1 sec cutoff to generate an envelope signal. The envelope signal is compared to a pre-defined reference level and a yes/no output is generated. Processing of signals above 1 Hz could be expanded to report multiple levels, signal frequency and amplitude, or peak values.

Motion Sensing

An accelerometer is included in the electronic circuit for motion sensing and sensing the orientation of the subject (e.g. standing, lying down). However the flex sensor may be used by the electronic circuit to provide a backup signal for the accelerometer. A possibly useful feature of the motion signal obtained from the respiration detector is that it is shows particular sensitivity to localized upper-body motions. This contrasts with the accelerometer, which is sensitive to any acceleration of the torso.

The electronic circuit may also include correlation of multiple sensor inputs, particularly of the respiration sensor and accelerometer. The primary intention is to provide improved confidence levels for the quality of processed signals. A simple example is that the apparent presence (or absence) of a detected respiration signal may be considered meaningless if a large accelerometer output in a similar frequency range is detected.

Sensor Electronics

The LSDS gathers certain physiological information and sends it first wirelessly to a local receiver or transceiver for retransmission to a separate computer station such as a PC or PDA. The unit measures heart rate by detecting and timing ECG R-waves, determines physical activity and orientation using an accelerometer, determines respiration rate by reading a chest expansion sensor, and measures temperature. These life signs are then analyzed using a health state determination algorithm. The resulting health indication, plus the raw data behind it, is transmitted out of the sensor every two seconds.

Major Component Overview

The sensor contains an 8-bit processor surrounded by various sensor inputs and an RF transmitter. A block diagram of the electronics is shown in Fig.**13.** The full circuit diagrams are presented in Figure 14 (Processor and Power Control), Figure 15 (ECG Front End), Figure 16 (Accelerometer and RF circuit), and Figure 17 (Respiration Circuitry).

Referring to Figure13, a microprocessor **49**such as an Atmel AVR Mega32 processor is used. Typical requirements for the processor are low power draw, large program memory (16K words), generous RAM size (2K bytes), EEPROM for non-volatile storage, general purpose I/O, analog inputs, external interrupts, versatile timers, high and low speed clocks (4 MHz and 32.768 kHz), flexible low-power sleep modes, in-circuit programmability, and easy to use development tools.

To conserve battery life, the processor makes extensive use of sleep modes. There are two crystals attached to the processor, one that runs at 4MHz, and one running at 32.768 kHz. The high speed crystal runs the processor when it is awake, and the lower-frequency crystal keeps the internal timers running when both awake and in the low-power standby mode.

A Lithium-Polymer (LiPoly) battery is used because of its high power density, various thin packaging options, and lack of memory effect (as is experienced with NiCad and NiMHd battery chemistries). The preferred battery used in the LSDS strap is rated at 560 mAHr.

The battery voltage is monitored by feeding ½ of the battery voltage into one of the processor's A/D inputs. This ½ Vbat is also used by the ECG detection circuitry and is a convenient voltage for monitoring battery health. A fully charged battery be at about 4.2V, and the battery will operate normally all the way down to 3.2V, at which point the circuit will be shut down to avoid erroneous reports. Beyond 3.2V the voltage will drop fairly rapidly when under load.

The output of the sensor is intended to be transmitted to a local receiver for further transmission to a more remote station. The RF Monolithic (RFM) TX6000 is a 916.5 MHz transmitter **53** that operates at 3V and draws < 10 mA when on and draws virtually no current when in sleep mode (between transmissions). A 1 kHz Manchester-encoded data stream is sent out the RF transmitter once every two seconds. The transmitter uses simple on-off keying, thus only drawing power when transmitting a "1".

Transmit range depends on the length and shape of the antenna, the orientation of the antenna, and how close the antenna is to the body and the electronics in the LSDS strap. Maximum range is about 50 feet.

A pair of conductive rubber pads **55** picks up the ECG signal generated by the heart. A single-ended input circuit (one input is ground) amplifies and filters the ECG input. An adaptive comparator looks for the high slew rate of the R-wave component of an ECG pulse, allowing the circuitry to detect strong and fast heart rates as easily as weak and slow ones. The analog "front end" is a slew rate detector circuit with sensitivity down to 0.15 mV when no appreciable noise is present. This analog circuitry draws very little current, allowing it to remain continuously powered-up when the LSDS is on-body.

An ADXL202E two-axis accelerometer **57** is used to detect both activity level and orientation. This version of the device puts out a pulse-width-modulated pulse train that is timed by the processor. It is turned on by the firmware only when read, and left off at all other times. Only one axis, the one that corresponds to the vertical axis when the

wearer is standing upright, is used. Thus the sensor can distinguish a standing subject from one lying down, but cannot tell on which side he/she is lying.

Respiration sensor and circuitry

Tension sensors **59** are built into each end of the LSDS plastic shell. These variable resistors change value as the chest expands and contracts. The LSDS circuitry changes this resistance into a voltage that is then frequency limited using a 0.25 to 2.5 Hz band pass filter. The resulting signal is then sampled by the processor using one of its built-in analog-to-digital inputs, while the rest of respiration sensing is handled in firmware.

The sensor has a nominal resistance of approximately 5K ohms. The resistance change at maximum load: approx. (-500) ohms. The required analog bandwidth is 0.06 Hz – 4 Hz. The low pass (4 Hz) cut-off matches the available 8 Hz sampling rate. This should be adequate, although 6-8 Hz appears to be optimum. A 1st order filter may be adequate for the 4 Hz cut-off. The sensitivity of the sensor falls off at higher frequencies. Aliasing of signals up to 10Hz will be correctly interpreted as body movement.

The high pass (0.06 Hz) cut-off has been chosen to match the slowest normal breathing rate. It is intended primarily to provide decoupling of the sensor's DC offset.

When the sensor is to be used to sense heartbeat, an analog bandwidth of approx. 20-25 Hz is required. Because this would most likely be used as an occasional "last resort" measurement, it may not be preferred to provide analog wave-shape detection. The microprocessor could simple sample at a 40-50 Hz rate for a period of 5 to 10 seconds and process the signal to determine whether a heartbeat is present.

A Maxim MAX6613 temperature sensor **61** is use to measure the temperature of the circuit board. Since the plastic LSDS enclosure is pressed snugly against the skin, the temperature read by the sensor tracks the true skin temperature after a short thermal delay period. The sensor has better than one degree C accuracy over a 5C to 50C range. The sensor converts temperature into a voltage in a very linear fashion, and this analog result is fed into one of the processor's A/D inputs. Since it draws so little power, it is left on when the strap is on-body.

Power control

In order to extend battery life to its fullest potential, the ability to turn sections of the circuitry on and off is crucial. Power switching is under control of the processor. Some devices have power control inputs (e.g. the RF transmitter), while other devices are turned on and off using a high-side low resistance FET switch. Power to these devices is gated by the FET transistors whose gates are attached to processor outputs.

Power Management

A simple representation of this power management scheme is shown in Figure 18.. Some switches will be closed whenever the LSDS is on-body, and other switches are closed only when needed. The leads-on detection circuitry **63** is always attached to power since the processor always needs to know when the LSDS strap has been put on-body or taken off-body. Similarly, the processor is also always powered up, although it enters a low-power mode whenever possible.

Program organization

The firmware program stored in the microprocessor is organized according to the major tasks that are to be performed. A task manager schedules the execution of each of the tasks. By having each task operate as a state machine, task switching can be done at a

very fast rate, resulting in the illusion that all tasks are running simultaneously. Fig. _ is a block diagram of the major tasks.

Each task has a different operating mode, depending on whether the strap is on- or off-body. In most cases nothing is done when the strap is off-body. When on-body is detected (and debounced) by the sleep manager tasks, all of the other tasks turn on certain circuitry (as needed), initialize certain variables, and begin to perform their respective functions.

R-wave monitoring

The heart rate algorithm receives an interrupt every time an ECG pulse is detected. Since EMG and electrical noise caused by skin stretching and ECG sensor contact motion all cause interrupts on the ECG input to the processor, the heart rate algorithm performs a good deal of filtering in order to isolate the desired R-wave pulses.

Orientation monitoring

Orientation is determined by looking at the value of the accelerometer. Since the accelerometer is calibrated to detect gravity, a +1G acceleration means the unit is upright, 0G indicates horizontal orientation, and somewhere in-between means the strap is at an angle. Orientation is only measured when the activity level is between low and none.

Activity monitoring

Activity is measured periodically in order to determine how much movement the user is experiencing. The accelerometer is turned on and sampled at a 4 Hz rate in order to reduce battery consumption. A sudden/short movement may be missed, but the next movement may be measured instead. This task simply looks for the highest amount of acceleration that is sampled, and holds this level for a few seconds, as a peak-hold circuit would operate.

Temperature monitoring

Since temperature is not expected to be changing at a fast rate, temperature is only measured every 15 seconds in order to save battery power. This task has multiple states since the process includes reading an A/D input channel and then converting the result into a temperature.

Respiration monitoring

The respiration monitor task samples the bandwidth limited chest expansion voltage at an 8 Hz rate, and then performs a simple analysis to determine when breathing is occurring. The algorithm first determines when the wearer is inhaling or exhaling. This is done by looking at the relative change in the sampled signal, effectively taking a first order derivative that removes the DC component of the signal. Once a binary signal (inhaling or exhaling) is produced, it is timed and analyzed for consistent behavior. If several similar (+/- 25%) timed breaths are seen, they are averaged together and used as the final respiration value. If no consistent breaths are seen in a 30 second period, the respiration rate is set to "unstable". If no chest expansion/contraction is seen for over a minute, respiration rate is set to zero.

Health state manager

This task runs an algorithm that determines the current health of the wearer based on all available physiological information. Recent historical physiological information is kept in an array and is used to determine both the health of the user and the confidence of the assessment of health. The resulting health state is not used on-board, but is instead simply transmitted as part of the RF packet.

RF manager

This task transmits data. Transmissions are repeated every two seconds. Whenever it is time to transmit a packet of data, the RF manager task simply gathers the most recent physiological information, calculates the appropriate checksum, and builds a packet of information for transmission. In order to maintain tight timing on the Manchester encoded data, a timer interrupt is used to shift out the actual data bits. In other words, once the packet has been built by the RF manager task, the timer interrupt takes over and shifts out all of the data with the appropriate timing.

Battery monitoring

The battery monitor task periodically measures the battery voltage level in order to determine the health of the battery. Since batteries tend to have a "knee" at which the voltage drops off rapidly, only a "low" and "not yet low" determination can reasonably be made. Any voltage above 3.6V is interpreted as a healthy battery. About 95% of the time the battery will be above this "knee" voltage". When the voltage drops below 3.6V, the battery monitor interprets this as a "low" indication. When the battery drops below 3.2V, the battery monitor changes its indication to "dead", meaning that there is not much time left before the strap stops operating. The exact timing for each of these battery levels depends on strap use, how well the battery was charged, and how old the battery is. In general, a fully charged battery will operate over two weeks on-body before entering the "low" state, the operate another hour or more before entering the "dead" state. Even then, the unit should continue with a "dead" battery for 10 minutes or more.

Sleep manager

This task reduces battery consumption by putting the unit into a power-saving sleep mode as often as possible. The firmware puts the processor to sleep even when the strap is on-body. The difference in sleep mode use between on-body and off-body operating modes is that when on-body, the unit wakes up more often (8 times a second). The sleep manager looks at all of the states of all of the tasks when determining if the unit can go to sleep. If all of the tasks are in their respective "idle" states, and no action-pending flags are set, the firmware instructs the processor to shut down the main 4 MHz clock and wait for a timer or interrupt event to wake it up again. The unit spends almost all of its time in a low-current sleep mode, even when on-body.

Miscellaneous functionality

There are three timers running in the background, two being at high speed and one being at a slower 8 Hz rate. None of the tasks described above run any more often than 8 times a second, allowing the processor to spend most of its time in sleep mode, when on-body. One high speed timer is free running and is used to measure short time intervals. The other timer is started and stopped as needed to provide additional timing resources.

Improved EMI rejection.

The Flex Sensor may act as antennae to pick up unwanted electro-magnetic noise. While the output signal may typically be filtered to remove this noise, it is usually preferable to minimize the initial noise pick-up. The standard Flex Sensor has one resistive and one conductive strip, joined at the end of the sensor opposite the contacts. Improved EMI rejection will result from a configuration with one resistive strip and two conductive strips. The conductive strips are placed on both sides of the resistive strip, and

all three strips are joined at the end opposite the contacts – now three contacts instead of two. In connecting to a circuit, the two contacts to the conductive strips are connected to a fixed voltage level, typically either ground or supply voltage, while the contact to the resistive strip is used as the output. By these means the output portion of the sensor is completely surrounded by a portion that acts as an EMI shield.

Improved moisture resistance.

The mode of operation of the Flex Sensor, in which micro-cracks open on the surface of the resistive coating, makes it inherently susceptible to moisture. Water and other liquids can flow into the micro-cracks, effective shorting these gaps in the conductor. In air, suspended water molecules and other suspended ionic particles may similarly enter the micro-cracks with similar results. A cover sheet with an adhesive backing may be used to protect the resistive element.

Reversed bending

Two Flex Sensor elements may be printed back-to-back on a single substrate. If the substrate is bent in either direction, one of the elements will increase in resistance. The two sensors may be monitored independently. Alternately, the two sensor may be wired in series and connected between two fixed voltages, thus creating a voltage divider. The voltage output of the divider, measured at the junction between the two elements will increase when the device is bent in one direction and decrease when it is bent in the other direction.

The fabrication process may be modified to change the operating range. Immediately after the resistive ink is applied the substrate is bent into a concave shape; the ink is on the inside surface and so its length contracts relative to the substrate. The ink is allowed to dry, the substrate is straightened, and the material is processed to produce micro-cracks. Because of the contraction of the ink the cracks will be partially opened when the sensor is straight. The operating range of the sensor is shifted to provide a useful output signal with bending in both directions.

Transmission

Although to reduce bandwidth, processing is preferably accomplished on the LSDS, some processing may be left for the host (receiver). The LSDS processor transmits amplitude and duration values for respiration cycles but does not apply any threshold tests. The host (receiver) has the task of determining whether the amplitude and duration values fall within acceptable limits.

A running average of the amplitude and duration values of the last four respiration cycles is transmitted to the host processor, rather than the values for the current cycle alone. This provides a more consistent output, but may introduce a degree on indeterminacy.

A small hysteresis value is applied to the respiration signal to minimize false "end of cycle" readings due to noise in the signal. The hysteresis value is dynamically adjusted based on the amplitude of the previous cycle.

Communications protocol requirements

The communications protocols in use by this system must provide error detection or correction codes to ensure that the data is received as sent. The protocols used must provide the capability to be assigned to an upstream unit, so that a set of sensors may be assigned to a single hub, and a set of hubs may be assigned to a single remote station.

A local protocol provides the transport of data between one or more sensors and a single hub. Since there may be many sensors, the local data packet format is extensible, not requiring changes to the hub to accommodate new sensor additions.
Gaps in the sensor data must be accounted for, either by providing a filler packet (of perhaps just a timestamp), or by the indication that the sensor is no longer communicating.

A distant protocol provides the transport of data between a hub, and the remote station. This protocol must allow for interruptions in the data stream, with later recovery of data stored within the hub.

User Interface Requirements

The hub subsystem may provide a limited user interface in order to provide local health display (e.g. red/yellow/green LED's), and possibly a local selection mechanism to facilitate the initial association of one or more sensors to a specific hub. The association of a specific hub to a remote station may be performed at the hub, or via the remote communications link, either to a medic PDA, or back to a remote station.

The remote subsystem has a more complex user interface to allow for the display of the basic status of multiple hubs within a single display, as well as being able to display additional status and data details from at least a single hub.

Medic PDA

The medic PDA subsystem has a user interface capable of displaying a list of hubs to connect to, and a mechanism to connect and display the detailed data as delivered by the hub.

Processing requirements

The sensor subsystem is designed to: Capture and convert the analog data into digital form, perform error detection processing, to validate the proper application and operation of the hardware systems, battery status, etc., perform combined analysis of the biometric data, yielding the overall health metric, assemble and transmit the periodic data packets to the hub subsystem, and accept data received from the hub subsystem, applying configuration or command sets to update operational parameters.

The hub subsystem is designed to: Collect the periodic data from the sensor subsystem(s), buffering samples for transmission to the remote station; Provide minimal user interface capabilities to display the overall health status, and allow for sensor subsystem selection to be performed; Perform additional health status processing if multiple sensors are available to a single hub; Provide the uplink processing and data packaging for remote/PDA accesses

The remote subsystem is designed to: Provide minimal status display of up to 20 hubs; Provide expanded status display of one selected hub; and Provide long-term data logging for all hubs connected.

The medic PDA subsystem is designed to : Establish a communications link to a single hub unit; and Provide display of all available sensor data and status information.

Communication Protocols

There are two communications protocols required as part of the complete LSDS design. The first protocol transfers data from the vital signs sensor to the hub, which in turn acts as a concentrator and gateway to a remote station.

The Sensor-Hub protocol provides the communications locally between one or more body-worn sensors, and a physically proximate hub/gateway.

Packet formats

General packet structure

Every packet is required to provide the indication of the start of packet, which is done by encoding the packet length, followed by the ones complement of the packet length as the first two bytes. The packet length is defined as the number of bytes (octets) of the data payload, plus two so that the 16-bit CRC is included in the length. The packet data payload follows the header, and is able to be up to 253 bytes in length. The validation CRC follows the payload data, and is a standard CCITT polynomial CRC.

Byte #	*Description*
0	*Packet length (n)*
1	*Ones complement of packet length (~n)*
2 through n	*Packet data payload*
N+1	*MS Byte of 16-bit CRC*
N+2	*LS Byte of 16-bit CRC*

Sensor to Hub payload format

There are two kinds of data transmitted from the sensor to the hub: sensor data and control data. Sensor data contains the data values obtained from one or more vital signs sensors that are present. Control data is sent in response to a command from the hub.

Sensor Data packet format

The format of a Sensor Data packet contains, at the minimum, the Sensor ID field, the first Data Present byte, and the health status field. If indicated in the data present field(s), other data will be present in the packet, in the order defined in the data present field.

Sensor ID 8 bits Assigned ID of sensor

The Data Present is one or more bytes, with a bit set for each position that is encoded in the packet.

First Data Present byte

Bit position	*Description*
0	*Health Status*
1	*Heart Rate*
2	*Breath Rate*
3	*Motion*
4	*Vocalization*
5	*Temperature*
6	*Battery Status*
7	*Clear indicates end of data field bytes*

Second Data Present Byte

Bit position	*Description*

0	*Unused*
1	*Unused*
2	*Unused*
3	*Unused*
4	*Unused*
5	*Unused*
6	*Unused*
7	*Clear indicates end of data field bytes*

The health status field is the output of the overall health algorithm. This output will take the form of a three-state variable, followed by an integer confidence rate. The heart rate field contains either the heart rate numeric value, in the range of 20-250 beats per minute, or an indication of a hardware or software problem status. The breath rate field contains either the breath rate numeric value, in the range of 1-100 breaths per minute, or an indication of a hardware or software problem status. The motion field contains the indication of activity, as measured by an accelerometer, and will be in a 4-state range where lower value indicates less activity. The vocalization field contains data from the sensor. The temperature field contains the current body temperature in degrees Celsius. The battery status field contains a three-state (high, medium, low) value indicating the charge left in the battery. The sensor control packet is sent in response to a command from the hub. Its contents are dependent on the command that it is responding to. The Sensor ID contains the 32-bit unique ID for a sensor. This is used as part of the process of associating a sensor to a hub.

The data transmitted from the hub to the sensor contains command data only. These messages are for providing configuration values, and retrieving status information that is not periodically transmitted.

Sensor Commands

Attach Sensor: This command causes the sensor to become associated with the sending hub, and assigns an 8-bit sensor id to the sensor.

16-bit CRC generation and validation: CRC generation is preferable to a simple checksum due to the larger number of errors that a CRC will catch, that a checksum will not.

Error handling

At a minimum, the CRC on each data packet will indicate the success or failure of data transmission. Any packet that fails the CRC check will be discarded, and will not used in determining either the state of the system, or the health of the person it is attached to. If the underlying transport protocol does not support error correction measures such as retransmission, then a data packet that fails its CRC check will be discarded, and an indicator of this data loss inserted into the data stream.

Hub-Remote protocol

The hub-remote protocol provides the information transfer between the hub, and a remote viewing station that may be either a medic PDA, or a grouped display.

Remote Display of Data

The software is divided into an upper and lower end, based at the point in which a valid packet has been received. In the case of a live connection, this is checked for in the timer loop once every 100 msecs, polling for new data received by the serial interface and

collecting it into a packet. In the case of a replay file, a two-second timer is used to read in the next packet 'received'.

A valid packet, whether from a file or from the serial interface, is passed to the main message loop of the application. When this is received, the packet is parsed, updating the corresponding displays with the newly received data. In addition, the data received is formatted into an ASCII string in hexadecimal format, and displayed in the LSDS communications field. Live connections additionally count the number of packets that contained header errors or checksum errors and update their respective fields.

If the health status algorithm is enabled, it will be sent copies of the newly received data, which are placed into individual parameter data buffers for the next analysis phase. Once per second, the health status algorithm is executed on the data buffers, updating the display of the health status, along with the confidence score of that determination.

Configuration dialog

The configuration dialog contains the controls to select between data input from a live sensor, and replay data from a log file, serial port setting controls for both the LSDS sensor, and the optional Propaq interface, and enable checkboxes for running a session with a Propaq collecting data, as well as enabling or disabling the local health status algorithm for processing on received data. It is preferred that when using the local health status algorithm, that a single ID be filtered for, as conflicting data from multiple sensors will invalidate the operation of the health status algorithm.

Main dialog

The main dialog is where all of the relevant information from data collection and processing are displayed. The dialog is broken up into groups of related data:

LSDS Communications displays provides a view of the communications from the LSDS sensor. As valid packets are received, the payload portion is displayed in ASCII hexadecimal notation within a scrolling text box. If header or checksum errors are detected, then the corresponding error counts are incremented.

Health Status displays contains the processed data from the LSDS sensor.. It also contains the display of the Health State and confidence score both from the LSDS sensor, as well as the local implementation of the algorithm.

The set of icons and the states they represent are as follows:

BLACK health state: this means that no data has been received for 16 seconds

BLUE health state: this means that a valid determination is unable to be processed from the current data.

RED health state: this means that the health state is in critical condition, or possibly dead.

Yellow health state: this means that the health state is abnormal.

Green health state: this means that the health state is normal.

Red exception health state: this means that one of the red exception states has occurred.

The Propaq comms display provides a single status line indicating the operational mode of the Propaq communications interface, display of the received HR and RR values from the Propaq, and the difference, if any, between those values and the values determined by the LSDS sensor.

Every time the application is run, the data delivered as valid packets is copied out to the text replay file. This occurs after the id filtering is applied, and will therefore correspond to the data trace of a single LSDS sensor unit if filtering is active. The format of the data is in human-readable ASCII hexadecimal notation, one line per packet. The format of the packet is documented in the RF protocol document.

LSDS Packet reception and validation

The incoming data is received and buffered by the system serial device driver. Once every 100 milliseconds, any incoming data is collected and scanned for the expected start of packet sequence as documented in the RF protocol document. Extraneous data bytes are discarded after being logged in the binary packet file. Once a valid start of packet sequence has been detected, a counter is incremented for each new data byte, until the expected number of bytes have been received. Once a complete packet has been collected, then the checksum algorithm sums the data values, and compares it to the expected checksum field. If it is equal, then the packet is sent on for processing as a valid packet, otherwise, the data is ignored, and a new start sequence is searched for.

LSDS data field processing

Each packet that has been validated contains essentially a snapshot of the LSDS sensor state. This data is validated against the expected range of values before being displayed, and if it is out of range, a display of ERR is used to indicate this. Additionally, if the alternate health status algorithm is active, then the data is sent to it to be used for evaluating the next health status result.

The ID data field is used only if sensor ID filtering is active. If the ID matches the filter ID, then the rest of the packet is processed, otherwise it is simply discarded. The Heartrate data field is used to display the current heartrate in the main dialog, as well as being subtracted from the most recent Propaq HR value to generate the delta HR field, if the Propaq interface is actively collecting data from a Propaq monitor. The Respiration data field is used to display the current respiration rate in the main dialog, as well as being subtracted from the most recent Propaq RR value, to generate the delta RR field, if the Propaq interface is actively collecting data from a Propaq monitor. The temperature data field is used to display the current skin temperature in the main dialog. The acceleration data field is used to select the appropriate label in the acceleration display in the main dialog. The orientation data field is used to select the appropriate label in the Orientation display in the main dialog. The Health status data field is the Health State as determined by the sensors' internal health state algorithm. It is used to determine the display in the Sensor Health State display on the main dialog. Confidence score data is the confidence score calculated by the sensors' internal health state algorithm. It is used to update the display in the Sensor Confidence field in the main dialog.

Health Algorithm implementation

The design of the health status algorithm contains five processing steps: Data Gathering and buffering; Data averaging and conversion from numeric/symbolic into qualified range data; Rule lookup processing; Confidence scoring; and Result display. Of these steps, the first one is done asynchronously due to the nature of the communications medium, and is driven by the reception of data packets from the LSDS sensor. A one-second timer drives the rest of the processing steps, with all steps running to completion and generating a new health status and confidence score.

Data gathering and buffering

Each parameter has a 16-deep FIFO ring buffer for the collection of data from the sensor. Each sample in this buffer has, in addition to the value field, two flags, one to indicate that data was received, and one to indicate whether or not the data is valid. The current sample index of these buffers is incremented once per second, whether or not data is received. As the current write index is incremented, the new sample index flags are cleared to indicate that no data is present. As LSDS sensor data is received, it is copied into the current sample index in the ring buffer. A minimal amount of processing is performed, only to determine if the data value is within the defined valid range of the sensor.

Conversion from source data to qualified data

Each parameter ring buffer is processed to provide the average value of the data within the ring buffer. For numeric parameters (HR, RR and Temperature), this is simply the arithmetic average (sum of the valid data values divided by the number of valid samples). For symbolic parameters (Acceleration and Orientation), this is done by counting the number of each enumerated value, and returning the one that has the greatest count. In the case of equal results, the enumeration with the lowest value is returned. This average value is then compared to the defined range boundaries, and the qualified data range value is returned.

Rules and rule processing

A rule contains a bitmap of qualified data range results for each parameter, along with a result state to be used when a match is found. Each parameter fields in a rule will contain at least one of the defined qualified data results, and may contain the composite result masks. Once the current states of the ring buffers has been obtained, these states are compared to each rule until either a match is detected, in which case the corresponding health state is used, or all rules have been checked, in which case the default state of BLUE is used.

Confidence scoring

The confidence scoring is performed last, since one of the input parameters is the determination of whether or not the current Health State has changed.

Once the health state and confidence score have been determined, then the new values are displayed on the main dialog, in the Hub Health State and Hub Confidence fields.

Heart Rate Calculation Algorithm

The algorithm works by tracking trends. A trend is defined as a somewhat consistent series of ECG pulses based on their timing. Several times a second a decision is made to keep using an existing trend or to shift to using a new trend. This means that several processes must be running in parallel, one that tries to track an already established trend, one that continuously looks for a new trend, and one that determines which of these two has better data. Incoming ECG information is filtered before presenting it to the trend tracking routines in order to avoid spending time working on noise pulses. ECG data is averaged and filtered, and then converted into an actual beats-per-second value.

A block diagram of this algorithm is shown in Figure 20. Since each incoming ECG pulse is time stamped, those remaining after filtering and noise cancellation can be processed in non-real-time. This is useful since past or future pulse information is

sometimes required to get a better understanding of the trend being followed and to allow for more tolerance of missing or extra pulses.

Timing

The slower the timebase, the easier it is to run the algorithm on a simple, 8-bit processor. Additionally, a timebase that uses a lower resolution clock allows the timebase to run while the processor is sleeping, reducing the drain on battery power. However, a more course timer resolution increases error (reduces accuracy) and makes it more difficult to implement simple per-beat timing comparisons.

A reasonable compromise is to use a 32 Hz clock as the basic timer. This allows per-beat intervals to be timed accurately enough to determine if a trend is present, shifted, or lost. Although a 32 Hz clock is not nearly fast enough to accurately time heart rate on a per-beat basis, the averaging/filtering scheme described below looks at 4 seconds or more of ECG data. With a window of 4 seconds, a 32 Hz clock allows for better than 0.8% accuracy. A 32 Hz timer allows for an 8-second duration when stored as a simple 8-bit entity. This is plenty long enough for all pulse timing and averaging activities.

Process timing

In order to keep processing power to a reasonable level and to allow the use of a small, inexpensive, and battery conscious microprocessor, processes are set up to run only at certain specific intervals, and this process repeat pace is kept to a fairly slow rate of once every eight seconds.

Figure 21 shows how often each process is run. ECG pulse detection is performed whenever an ECG (or EMG or other unwanted signal) is seen, so its timing is sporadic and asynchronous to the rest of the process timing. The heart of the algorithm, which includes filtering trend tracking and analysis, is executed at an 8 Hz rate. Averaging/filtering is run only once every two seconds, and the resulting ECG rate is converted to a beats-per-second value every two seconds as well.

Algorithm specifics

ECG, EMG and any other electrical impulse of sufficient magnitude cause an interrupt to the processor. The ECG pulse detection routine simply timestamps every interrupt and saves a record of its having happened. This information is used by the filter process. A flowchart of the ECG pulse detection interrupt is shown in Fig.22. Since an incoming noise stream should not be allowed to flood the filtering process, the ECG pulse detection routine stops recording interrupts if too many ECG pulses are still waiting processing by the filtering process. The list of pending interrupts is cleared by the filtering routine on a periodic basis.

Low pass filter and noise cancellation

This process removes presumably incorrect ECG information by applying low pass filtering and noise cancellation. A low pass filter does not allow ECG pulses to come in too close in time to previous pulses, whereas noise cancellation simply deletes what appear to be extra pulses.

The low pass filter cutoff frequency is set to 8 Hz, which corresponds to a two-times sampling rate of 240 BPM. The filter works by throwing out incoming pulses that occur too close to the previous pulse. Since the filtering routine is run at an 8 Hz rate, the routine allows only one ECG pulse per 1/8 second period. If more that one ECG pulse is pending processing, only one is taken and the rest are ignored. A good example

of when this filter is necessary is when there are echo ECG pulses due to both R and P wave detection. A flowchart of this filter is shown in Figure 23.

Note that since this algorithm looks 1/8 second backward in time, a 1/8 second delay is introduced by this scheme. Once the ECG pulses have been processed, pulses seen in the previous 1/8 second window are passed on to the trend discovery and trend tracking stages of the algorithm.

As an example of how this filtering scheme works, refer to Figure 25. The first labeled pulse is ignored since it occurs too close to the proceeding pulse. The second labeled pulse is ignored since it is an additional pulse within the same 1/8 second time window.

Look for a new trend

New trends are recognized by looking at only the most recent ECG pulse timing. A trend is defined as somewhat consistent timing of ECG pulses. Since noise can be expected and ECG pulses may occasionally be missed, the trend acquisition algorithm needs to be tolerant of extra and missing pulses. This is accomplished by looking at intra-beat timing and deciding which timing appears most often. As long as extra or missing pulses do not appear more often than true ECG pulses, this process should be able to find the correct heart rate.

The algorithm works by looking at four most recent inter-beat intervals and developing a scoring based on the consistency of these intervals. Since inter-beat intervals are not going to be exactly the same, a +/- 12.5% window is allowed. With this size window, a missing beat will clearly be detected, and although an extra beat may appear inside this window, the following correct beat will appear later in time much less than the window size.

By looking at only the last four inter-beat intervals, the effect is that of a sliding window, leaving older information behind quite soon. This allows the algorithm to lock onto new trends fairly quickly, and also allows it to track slightly changing heart rates. Each new ECG pulse or perceived missing ECG pulse causes an update in the "score" for how well a trend is being seen. *The rules for scoring are as follows:*

- *if 3 in a row have similar timing, score = high*
- *if 3 of last 4 have similar timing, score = med. high*
- *if 2 of last 3 have similar timing, score = medium*
- *if 2 of last 4 have similar timing, score = low*

Using Fig.25 as an example, inter-beat intervals are tracked as they occur, left to right. Interval t_1 is the normal heart rate, and it appears the most. When the extra pulse occurs, it creates the two shorter inter-beat intervals t_2 and t_3. Then, when a later pulse is missed, the longer inter-beat interval t_4 is seen.

In order to keep extra or missing pulses from adversely affecting the heart rate being calculated by the averaging process, only the consistent inter-beat intervals are saved in the history array. Again referring to Fig. _, since t_1 is seen the most, only it will be saved in the history array.

A flowchart of this trend-acquiring process is presented in Figure 26.

Tracking an existing trend

An existing trend is tracked by assuming the heart rate to be at a certain frequency, and then looking for more heartbeats at these expected intervals. Extra pulses are ignored in order to keep locked onto an existing trend in the presence of noise (extra pulses). Likewise, missing pulses are accommodated by assuming pulses to come at a certain time, and to allow for missing pulses as long as they sooner or later start showing up at the expected time. These actions are illustrated in Figure 27.

In order to keep locked onto a slowly changing heart rate, a 12.5% window (+/- 6.25%) of tolerance is allowed on each expected pulse. This size is selected since it is easy to calculate in integer math. With a tolerance window this wide, the heart rate can change at a reasonable rate while still allowing this process to remain locked onto the moving trend.

Since extra pulses are ignored and missing pulses are assumed present, a near or perfect harmonic shift in heart rate will not be noticed by this process. For example, a jump from 60 to 120 BPM will not be noticed since at 120 BPM, a pulse is seen at the same timing as when the heart rate was 60 BPM, and the extra pulse in the middle is simply ignored. This indifference to harmonic shift is acceptable since a "look for a new trend" process will identify the proper heart rate of 120 BPM, and its score will be higher than that generated by this process.

Also, there needs to be a mechanism by which this "existing trend" process is locked onto a new trend when that new trend is seen to be strong and stable. The mechanism works by unlocking the existing trend when its score is low, and then locking onto a new trend when the new trend is seen to exist. This is how a harmonic shift is ultimately resolved, forcing the existing trend to lock onto the new, correct trend.

A score is maintained for how well the trend is being tracked. *The rules for scoring are as follows:*

- *if 4 of the last 4 expected pulses were seen, score = high*
- *if 3 of the last 4 expected pulses were seen, score = med. high*
- *if 2 of the last 4 expected pulses seen, score = medium*
- *if 1 or 0 of the last 4 expected pulses seen, score = low*

An array of inter-beat intervals is maintained in order to provide the averaging process the information it needs. In order to keep missing or extra pulses from skewing the averaging process, extra pulses are not recorded in the history array, and missing pulses are assumed present and are inserted into the history array.

The algorithm is simplified by recognizing the fact a maximum of one pulse can be seen or expected every time this process is run (8 times a second). A flowchart of this trend-tracking process is shown in Figure 28.

Decide which trend to use (if any)

This process decides which set of inter-beat periods to use when calculating the heart rate. The scores generated by the "look for a new trend" and "track existing trend" processes indicate which array of historic inter-beat values are of higher quality, so the

scores alone are the mechanism for making this decision. If both scores are the same, the historic data for the existing trend is used since it has a tighter tolerance on how much an inter-beat interval can change from beat to beat.

Since a good score will not always be available from either or both trend analysis processes, this process has two additional modes of operation. First, if both the trend the trend tracking and acquisition processes have low scores, the heart rate status is set to "unstable". Second, if there are no heartbeats but the ECG contacts are determined to be on-body, then the heart rate status is set to "none".

If neither trend contains useful information, this trend selection process makes two key decisions. First, if there have not been any heart beats in a while, the heart rate is set to zero. A timer is managed in the "low pass filter and noise cancellation" process that is cleared when an ECG pulse is detected and incremented when no pulse is seen. Since that process is run every 1/8 second, the "no pulse" timer therefore counts at an 8 Hz rate. If the count exceeds a certain threshold, the pulse rate is set to zero and the rest of the trend selection process is skipped. Second, if either of the trend tracking processes has a low score and it is indicating missing pulses, the heart rate is set to a "slow heart rate" status.

Averaging filter

The averaging filter works by looking at the previous 4 to 6 seconds of inter-beat timing intervals. Faster heart rates will therefore be averaged over a larger number of beats than slower rates, but even at a low-end 30 BPM heart rate, three pulses can averaged in a 6-second window.

The algorithm simply looks back in time through an array of historic inter-beat intervals until it sees at least 4 seconds of pulse timing, and then averages this most recent pulse timing. The filter is run once every two seconds, so updated averaged hear rates are available every two seconds. Since only the most recent "good" inter-beat intervals are used in the formula, missed pulses will not have an impact on the algorithms ability to generate new averages every 2 seconds.

The coarseness of the 32 Hz timebase does not compromise accuracy as long as inter-beat intervals extend over a 4 second period of time. Each of the inter-beat intervals in the historic array of values taken alone is not very accurate, but when added together, their round-off inaccuracies cancel out.

A sample averaging scenario is shown in Fig.29. The heart rate is about 55 BPM, which corresponds to an inter-beat interval of about 35 counts (since the timer is running at 32 Hz). The most recent inter-beat interval is seen to be 34. Moving back far enough to get at least 4 seconds of heart beats (4 x 32 = 128 total counts) takes one back to an inter-beat interval of 33. The average counts is therefore (34 + 36 + 35 + 33) / 4 = 34.5 counts.

A final low pass filter stage is added that limits how fast the heart rate can change. This is present to reflect the realities of physiology. A large step change in heart rate could imply an error in the new heart rate, so the rate at which the heart rate that is shared with the outside world is allowed to approach the calculated heart rate based on the old and new trends is limited to 4 BPM per second. As an example, if the previous heart rate was 60 and the newly calculated heart rate is 72, the heart rate sent out of the Life Signs Detection System will be 64, then 68 one second later, then 72 a second after that.

The math required to convert the filtered (averaged) inter-beat interval to a beats-per-second heart rate is simple. Since there are 32 clock ticks per second, the heart rate is (32 / avg. inter-beat interval) * 60. For the example above, this works out to (32 / 34.5) * 60 = 55 BPM.

Remote Communication

A sensor in the Life Signs Detection System (LSDS) communicates with a health hub (some kind of PC).

The wireless network connects a single sensor to a health hub via a receiver as shown in the diagram below. The range is preferred to allow for reliable operation at 20 feet. The receiver manages the decoding of the data stream being received from the sensor. The link from the receiver to the health hub is simple serial RS232 at a 9600 baud rate as shown in Figure 30. The health hub may be any small device having a processor, preferably a PC (desktop or laptop) or a PDA.

Physical layer

A simple, low cost RF transceiver operating at 900 MHz may be used at both ends of the wireless link. Versions using transceivers would be capable of two-way communication.

Data link layer

Low cost RF modules tend to have two specific problems. First, as they are susceptible to noise, particularly in the absence of a transmitted signal, receivers tend to have noise pulses at random times. This means that the RF modules are not suited for sending asynchronous data. Second, the RF modules appear unable to hold a "high" level for longer than 10 or 15 milliseconds. This is most likely due to AGC circuitry. The modules therefore seem more content to see constantly changing data.

One solution to these two shortcomings is to Manchester encode the data being sent through the RF channel. This not only forces the data to change very often, but it reduces the sensitivity to noise. The bit rate will be 1 msec, and a "0" is encoded as a rising edge (01) in the middle of the bit time, and a "1" is encoded as a falling edge (10). An example bit stream is shown in Figure 31:

In order for the receiver to recover the timing of the bit stream and hence understand when the start and middle of the bit time is, the transmitter must precede the actual data packet with a series of all 0's. The receiver will recover the bit timing by looking for consistent falling edges. The exact number of 0's in this leader is not important as long as it generates enough clock edges for the receiver to lock onto it. Eight to 16 bits should be fine. An all 0's leader corresponds to the encoded data stream shown in Figure 32:

Application layer

Physiological information is transmitted out of the sensor on a periodic basis. This information is sent in packets in order to provide error detection and noise immunity. The packet format is:

[leader] [header1] [header2] [data] [checksum]

The header is a 16-bit pattern that allows the receiver to identify the start of a valid packet. The 10-byte data field is a number of bytes that describe the physiological condition of the wearer of the sensor. Lastly, the checksum is a 16-bit code that helps determine if the data was received without error. *Header1 is 0x0d, while header2 is 0x1c. The 10-byte data field is encoded as follows:*

byte 1 = sensor ID (valid range is 1 through 250)
byte 2 = health status, where
0 = black (no sensor data available)
1 = blue (uncertain or unreliable data
2 = red (health is very poor)
3 = yellow (health is marginal)
4 = green (A-OK)
byte 3 = activity level, where
0 = no activity
1 = low level of activity (e.g. slow rolling, deep knee bends)
2 = medium level of activity (e.g. walking)
3 = high level of activity (e.g. running)
byte 4 = temperature, signed integer, in degrees C
byte 5 = heart rate, where
0 through 240 = heart rate, in beats per minute
250 = strap leads off
251 = strap leads on, but cannot determine heart rate due to too many extra pulses (e.g. noise)
252 = strap leads on, but cannot determine heart rate due to too many missing pulses (e.g. ECG signal level too low)
byte 6 = battery voltage status, where
0 = high
1 = moderate
2 = low
byte 7 = orientation, where
upper 4 bits = up/down axis, where
0000 = not stable enough to determine orientation
0001 = upright
0010 = slanted
0011 = horizontal
0100 = inverted
lower 4 bits = side-to-side axis
byte 8 = respiration rate, where
0 through 100 = respiration rate, in breaths per minute
250 = cannot determine respiration rate (e.g. too much noise)
byte 9 = confidence score of the overall health state assessment
byte 10 = spare byte available for debug, testing, or future use

The checksum is a 16-bit summation of each of the data bytes. The summing is done byte-wide, but the result is 16-bIts wide.
All multi-byte entities are transmitted little-endian (lowest byte first). The only data that is affected by this rule is the 16-bit checksum since all other protocol elements are bytes.
Orientation is interpreted using the diagram of Figure 33:

Health State Assessment Algorithm

The clinical health state assessment algorithm for use in the Life Signs Detection System (LSDS) combines raw data collected by the LSDS sensors to determine the following information:

- Physiologic State – Acquire and analyze physiological data to classify general wellness and rule out a physiologic state consistent with death
- Decision Confidence Score – Calculate an indicator of diagnostic certainty
- Multi-Tier Processing – Using a revised rule set, calculate physiologic state and confidence score; using a rules set based on one's personal baseline, calculate a physiologic state and confidence score

Triage Indicators – Acquire, analyze, and report appropriate collection of life sign parameters to support specific diagnostic assessments.

Algorithm Inputs

The table below lists the data available from the sensor for use in the algorithm, along with error conditions:

Table 1. LSDS Platform Parameters and Error Conditions

Sensor	Primary Life Sign Parameter	Additional Data	Error Conditions from Sensor
R-Wave Detector	HR	Presence of signal (Yes or No) Heart rate variability	Leads Off Noisy Lead Signal not detected Out of range – high Out of range – low Sensor INOP
Temperature Sensor	Temp (an estimate of core body temperature value based on External Body Temperature as affected by ambient temperature)	External body temperature	Signal not detected Out of range – high Out of range – low Sensor INOP
Accelerometer	Speed of motion (None, Slow, Medium, High, or Off-scale Shock)	Body Position (Vertical/Upright, Vertical/Upside-down, Horizontal)	Sensor INOP
Respiration	Presence of Respiration (Yes or No)	Respiration Rate Tidal volume indicator Time since last breath Presence of motion	Bad signal (voltage too high or too low) No breath detected Out of range – high Out of range – low Sensor INOP
Other Information from Sensor Platform	Platform ID (device serial number, or possibly soldier ID number)	Time Stamp of data packet	Low Battery

Algorithm Outputs

The algorithm is required to produce the following information based on continuous processing of raw sensor data:

- A color-coded health state classification (green for alive, red for possibly not alive)

- An indicator of extent of confidence in the accuracy of the health state classification (i.e., "diagnostic certainty").

Health State Classifications

The table below defines the required health state classifications:

Table 2. Health State Classification Descriptions

Overall Health State	Color Code
Alive	Green
Alive, but significantly outside "normal"	Yellow
Dead	Red
Uncertain (Incomplete or conflicting information from sensors)	Blue
SENSOR PLATFORM NOT OPERATING (Determined by receiving platform, e.g., no data received at for a given prolonged interval)	Black

Confidence Score

The confidence score represents level of confidence in the accuracy of a given health state decision. The calculation for confidence score is based on the probability (percentage of likelihood) that a given health state assessment (Green/Alive, Yellow/Alive-Not-Normal, or Red/Dead) is accurate.

Life Signs Data Prioritization

Data prioritization is used to determine the order for proceeding through the algorithm's data interpretation rules. Prioritization provides an abstraction of the order in which an on-site clinician would examine LSDS life signs data. Prioritization also allows a "value level" to be assigned to individual life signs (from "high value" to "low value") as an indication of usefulness in determining health state. The value will be considered in computing a confidence score for each health state assessment decision.

The LSDS data is prioritized as follows, based on usefulness of each parameter compared to traditional vital signs monitoring including visual patient inspections.

1. Heart Rate – Numerical, traditional measurement of heartbeat; high value
2. Respiration Rate – Numerical, traditional measurement of breathing; high value
3. Speed of motion (None, Slow, Medium, or Fast), substitutes for visual observation of activity (e.g., Fast might be assumed to equal running, and can be used to justify high heart rate); medium value
4. External Body Temp – Skin temperature influenced by ambient temperature (weather, garments, etc.); correlation to core temperature (traditional measurement). Skin temp can be useful in remote assessment situation where user's environmental conditions are known to assessment personnel (or post-processing software). Low value.

5. Position of body – substitutes for visual observation of standing or lying down; (e.g., sleeping could result in position of lying down, along with slowed respiration rate and speed of motion at NONE); low value

Interpretation Rules for "Green" and "Red" Health States

This section lists the interpretation rules that support the decisions for the Alive/Green-Normal and Dead/Red states. The Alive/Yellow-Not-Normal state and the Uncertain/Blue states are addressed in separate sections below.

Each rule is stated in terms of specific life sign parameters (breadth of data) and length of observation time (duration of monitoring).

The table below summarizes the rules that apply to current Alive/Green and Dead/Red states.

Table 3. Life Signs Interpretation Rules for Alive/Green and Dead/Red States

Available Parameters	Interpretation Rule	
	Alive/Green	**Dead/Red**
HR only	HR ≤ 160 BPM and HR ≥ 40 BPM for 8 seconds or more	HR = 0 for 4 minutes or more HR <30 BPM for 10 minutes or more
RR only	RR ≤30 breaths/minute and RR ≥ 8 breaths/minutes for 8 seconds or more	RR = 0 for 5minutes or more
Acceleration/Position only	Insufficient to determine this state	Insufficient to determine this state
Temp only	Insufficient to determine this state	Insufficient to determine this state
HR and RR	[HR ≤ 160 BPM and HR ≥ 40 BPM and (RR ≤30 breaths/minute and ≥ 8 breaths/minutes)] for 8 seconds or more	HR = 0 and RR = 0 for 4 minutes or more
HR and Acceleration/Position	(HR ≤ 160 BPM and HR ≥ 40 BPM) and any acceleration value and any position value for 8 seconds or more (HR > 160 /BPM and HR ≤ 220 BPM) and (Acceleration is Medium or Fast for any Position value) for 8 seconds or more	HR = 0 and Acceleration is NONE (for any position value) for 4 minutes or more
HR and Temp	(HR ≤ 160 BPM and HR ≥ 40 BPM) and (Temp = NORMAL) for 8 seconds or more	HR = 0 and Temp ≠ NORMAL for 4 minutes or more
RR and Acceleration /Position	RR ≤30 breaths/minute and RR ≥ 8 breaths/minutes and any acceleration value and any position value for 8 seconds or more [(RR >30 breaths per minute and RR ≤ 45 breaths per minute) and Acceleration is Fast, for any Position value)] for 8 seconds or more	RR = 0 and Acceleration = NONE (any Position value) for 5 minutes or more
RR and Temp	RR ≤30 breaths/minute and RR ≥ 8 breaths/minutes and Temp is	RR = 0 and Temp ≠ NORMAL for 5 minutes or more

	NORMAL for 8 seconds or more	
Acceleration /Position and Temp	Insufficient to determine this state	Insufficient to determine this state
HR, RR, and Acceleration /Position	[(HR ≤ 160 BPM and HR ≥ 40 BPM) and (RR ≤30 breaths/minute and RR ≥ 8 breaths/minutes) and (any acceleration value and any position value)] for 8 seconds or more [(HR > 160 /BPM and HR ≤ 220 BPM) and (RR >30 breaths per minute and RR ≤ 45 breaths per minute) and Acceleration is Fast, for any Position value)] for 8 seconds or more	[(HR = 0) and (RR = 0) and (Acceleration is NONE for any Position value)] for 4 minutes or more
HR, RR, and Temp	[(HR ≤ 160 BPM and HR ≥ 40 BPM) and (RR ≤30 breaths/minute and RR ≥ 8 breaths/minutes) and (Temp is NORMAL)] for 8 seconds or more	[(HR = 0) and (RR = 0) and (any Temp ≠ NORMAL)] for 4 minutes or more
HR, Acceleration/Position and Temp	[(HR ≤ 160 BPM and HR ≥ 40 BPM) and (any acceleration value and any position value) and Temp is NORMAL]for 8 seconds or more [(HR > 160 /BPM and HR ≤ 220 BPM) and (RR >30 breaths per minute and RR ≤ 45 breaths per minute) and (Acceleration is Fast, for any Position value) and Temp is NORMAL] for 8 seconds or more	[(HR = 0) and (Acceleration is NONE for any position value) and Temp ≠ NORMAL)] for 4 minutes or more
RR, Acceleration /Position and Temp	[(RR ≤30 breaths/minute and RR ≥ 8 breaths/minutes) and (any acceleration value and any position value) and Temp is NORMAL] for 8 seconds or more [(RR >30 breaths per minute and RR ≤ 45 breaths per minute) and (Acceleration is Fast, for any Position value) and Temp is NORMAL] for 8 seconds or more	[(RR = 0) and (Acceleration = NONE for any Position value) and Temp ≠ NORMAL)] for 5 minutes or more
HR, RR, Acceleration /Position and Temp	[(HR ≤ 160 BPM and HR ≥ 40 BPM) and (RR ≤30 breaths/minute and RR ≥ 8 breaths/minutes) and (any acceleration value and any position value) and Temp is NORMAL] for 8 seconds or more [(HR > 160 /BPM and HR ≤ 220 BPM) and (RR >30 breaths per minute and RR ≤ 45 breaths per minute) and Acceleration is Fast, for any Position value) and Temp is NORMAL] for 8 seconds or more	[(HR = 0) and (RR = 0) and (Acceleration is NONE for any Position value) and Temp ≠ NORMAL] for 4 minutes or more

INTENTIONALLY BLANK

Interpretation Rules for Alive/Yellow State

Given the life signs data available from the LSDS sensor platform, the Alive/Yellow-Not-Normal state indicates that at least one "high value" parameter, either HR or RR, is outside the normal range for a sustained time interval. The table below lists the interpretation rules that support the decisions for the Alive/Yellow-Not-Normal state.

Table 4. Life Signs Interpretation Rules for Alive/Yellow State

Available Parameters	Interpretation Rules
HR only	[(HR < 40 BPM and HR ≠ 0 BPM) or (HR> 160 BPM)] for 8 seconds or more
RR only	[(RR<8 breaths/min and RR ≠ 0 breaths/min) or RR > 30 breaths/min)] for 8 seconds or more
Acceleration only	Insufficient to determine this state
Temp only	Insufficient to determine this state
HR and RR	[(HR < 40 BPM and HR ≠ 0 BPM) and/or (HR> 160 BPM) or (RR<8 breaths/min and RR ≠ 0 breaths/min) or RR > 30 breaths/min)] for 8 seconds or more
HR and Acceleration	[(HR < 40 BPM and HR ≠ 0 BPM and any acceleration value) or (HR> 160 BPM and Acceleration is NONE)] for 8 seconds or more
HR and Temp	[(HR < 40 BPM and HR ≠ 0 BPM for any Temp value) or (HR> 160 BPM and Acceleration < Medium for any Position value and any Temp value)] for 8 seconds or more
RR and Acceleration /Position	[(RR<8 breaths/min and RR ≠ 0 breaths/min and any acceleration value and any position value) or (RR > 30 breaths/min and Acceleration < Medium for any Position value)] for 8 seconds or more
RR and Temp	[(RR<8 breaths/min and RR ≠ 0 breaths/min and any Temp value) or (RR > 30 breaths/min and any Temp value)] for 8 seconds or more
Acceleration /Position and Temp	Insufficient to determine this state
HR, RR, and Acceleration /Position	[(HR < 40 BPM and HR ≠ 0 BPM) and/or (RR<8 breaths/min and RR ≠ 0 breaths/min) for any Acceleration value and any Position value] for 8 seconds or more [(HR> 160 BPM and/or RR > 30 breaths/min) and Acceleration < Medium for any position value] for 8 seconds or more
HR, RR, and Temp	[(HR < 40 BPM and HR ≠ 0 BPM) and/or (RR<8 breaths/min and RR ≠ 0 breaths/min) and any Temp value] for 8 seconds or more [(HR> 160 BPM and/or RR > 30 breaths/min) and any Temp value] for 8 seconds or more
HR, Acceleration/Position and Temp	[(HR < 40 BPM and HR ≠ 0 BPM and any acceleration value and any Temp value) or (HR> 160 BPM and Acceleration < Medium and any Temp value)] for 8 seconds or more
RR, Acceleration /Position and Temp	[(RR<8 breaths/min and RR ≠ 0 breaths/min and any acceleration value and any position value and any Temp value) or (RR > 30 breaths/min and Acceleration < Medium for any position value and any Temp value)] for 8 seconds or more
HR, RR, Acceleration /Position and Temp	[(HR < 40 BPM and HR ≠ 0 BPM) and/or (RR<8 breaths/min and RR ≠ 0 breaths/min) for any Acceleration value and any Position value and any Temp value] for 8 seconds or more [(HR> 160 BPM and/or RR > 30 breaths/min) and Acceleration < Medium for any Position value and any Temp value] for 8 seconds or more

Interpretation Rules for Uncertain/Blue State

All combinations of parameter values not covered in Tables 3 and 4 automatically fall into the Uncertain/Blue state.

Algorithm Boundary Conditions

This section describes the boundary conditions applied to the LSDS health state assessment algorithm.

"Normal" Data Ranges

The table below lists the data ranges that define the highest and lowest values the sensor can calculate (see Data Description column) and the "Normal" data ranges for individual LSDS signals.

Table 5. LSDS Alive/Normal Soldier Data Ranges

Sensor	*Parameter*	*Data Description (Raw Data Range)*	*"Normal" Range*
R-Wave Detector	*Heart Rate*	*Numeric (0 BPM, and 15 – 250 BPM)*	*40 – 160 BPM*
	Presence of Heartbeat	*Boolean (T or F)*	*TRUE*
Respiration Detector	*Presence of Respiration*	*Boolean (T or F)*	*TRUE*
	Respiration Rate	*Numeric (0 – 60 breaths/min)*	*8 – 30 breaths/min*
	Tidal Volume Indicator (High, Medium, Low)	*Integer (2, 1, 0)*	*High, Medium or Low*
	Time Elapsed Since Last Breath	*Numeric (0 – TBD seconds)*	*Not applicable*
	Presence of Motion	*Boolean (T or F)*	*TRUE or FALSE*
Accelerometer	*Speed (None, Slow, Medium, Fast)*	*Integer (0, 1, 2, or 3)*	*0 - 3*
	Position (Upright, Horizontal, or Upside-Down)	*Signed Integer (1, 0, or –1)*	*0 - 1*
Temperature sensor	*Estimated Core Temperature*	*Numeric (0 - 50°C)*	*NORMAL (36.4°C – 38.9°C)*
	External Temperature	*Numeric (0 - 50°C)*	*Not applicable*

Abnormal High and Abnormal Low Data Ranges

An intermediate ALIVE/YELLOW state provides a first step towards supporting remote triage. For the LDSD sensor platform, the ALIVE/YELLOW state can be characterized by the following conditions persisting over an appropriate time interval:

- *HR is outside of normal range (non-zero, higher or lower than normal range)*
- *RR is outside of normal range (non-zero, higher or lower than normal range)*
- *"History" data (trend) indicates a rate of change of physiological state that correlates with certain know injury conditions (e.g., exsanguination)*
- *Absolute external temperature is not below TBD*

The resulting abnormal data value ranges are shown in the table below:

Table 6. LSDS Alive/Not-Normal Soldier Data Ranges

Parameter	*Abnormal High*	*Abnormal Low*
HR	*161 and higher*	*39 and lower*
RR	*31 and higher*	*7 and lower*
Skin Temp	*>39°C*	*<36°C*
Acceleration	*Not Applicable*	*Not Applicable*
Position	*Not Applicable*	*Not Applicable*

Algorithm Details

This section describes the resulting health state assessment algorithm.

Overview

The algorithm involves two sequential steps that are repeated for each decision interval (the last 16 seconds, in the case of the LSDS sensor platform), each time a new data packet is received (every two seconds, in the case of the LSDS monitor), and for each tier of processing in use. The steps are as follows:

- **Translate sensor data to a health state decision** - Based on the valid sensor data received in the last 16 seconds, find the rule set and corresponding implied state.
- **Estimate the "goodness" of the new decision** - Based on the likelihood of the new state transition (previous state compared to new state), the persistence in the new state and the number and priority of parameters received for the new state, produce an appropriate confidence score.

Note that the multi-tier nature of the algorithm lies in its ability to apply multiple rules set for multiple usage categories (embedded in on-body device, modified base rules set for general population, modified rules set for personal health baseline).

Translate Sensor Data to a Health State Decision

The basic clinical rules set for the LSDS monitor have been restated in decision matrices (Tables 8 - 11) that correspond to the number of parameters received in a decision interval. Note that, although the basic rules set primarily uses 8 second intervals for state determination, the algorithm uses a 16-scond interval. This is because the physicians' rules consider the availability of new vital signs data in traditional monitors, typically

eight or more data samples at 1-second intervals. The algorithm's 16-second interval is an effort to increase the likelihood of having at least 8 data samples from the LSDS monitor, which delivers data at 2-second intervals.

Table 8. Decision Matrix for Only One Parameter in Last 16 Seconds

Parameter	Value	New State	Value	New State	Value	New State	Value	New State
HR	Normal	Alive	Abnormal	Alive-Not-Normal	0 BPM	Dead	Present, can't calculate	Uncertain
RR	Normal	Alive	Abnormal	Alive-Not-Normal	0 breaths per min	Dead	Present, can't calculate	Uncertain
Acceleration	Any	Uncertain						
Position	Any	Uncertain						
Temp	Any	Uncertain						

Table 9. Decision Matrix for Two Parameters Over the Last 16 Seconds

Parameters	Average Value Range 1	Average Value Range 2	Average Value Range 3*	New State
HR and RR	Normal	Normal		Alive
	Normal	Abnormal		Alive
	Normal	0		Alive/Not Normal
	Abnormal	Normal		Alive/Not Normal
	Abnormal	Abnormal		Alive/Not Normal
	Abnormal	0		Alive/Not Normal
	0	Normal		Alive/Not Normal
	0	Abnormal		Alive/Not Normal
	0	0		Dead
HR and Acceleration/Position	Normal	Any	Any	Alive
	Abnormal High	Fast	Any	Alive
	Abnormal High	Non-Fast	Any	Alive/ Not Normal
	Abnormal Low	None	Any	Alive/Not Normal
	Abnormal Low	Non-zero	Any	Alive/Not Normal
	0	Any	Any	Dead
HR and Temp	Normal	Normal		Alive
	Normal	H or L		Alive/Not Normal
	Abnormal	Normal		Alive/Not Normal
	Abnormal	H or L		Alive/Not Normal
	0	Any		Dead
RR and Acceleration/Position	Normal	Any	Any	Alive
	Abnormal High	Fast	Any	Alive
	Abnormal High	Non-Fast	Any	Alive/Not Normal
	Abnormal Low	None	Any	Alive/Not Normal
	Abnormal Low	Non-zero	Any	Uncertain
	0	Any	Any	Dead
RR and Temp	Normal	Normal		Alive
	Normal	Abnormal		Alive/Not Normal
	Abnormal	Normal		Alive/Not Normal
	Abnormal	Abnormal		Alive/Not Normal
	0	Normal		Dead
	0	Abnormal		Dead
Temp and Acceleration	Any	Any	Any	Uncertain

*Note that the third value range is only filled in for acceleration (acceleration and orientation).

Table 10. Decision Matrix for Three Parameters Over the Last 16 Seconds

Parameters	Average Value Range 1	Average Value Range 2	Average Value Range 3	Average Value Range 4*	New State
HR, RR, and Acceleration	Normal	Normal	Any	Any	Alive
	Normal	Abnormal	Any	Any	Alive/Not Normal
	Normal	0	Any	Any	Alive/Not Normal
	Abnormal High	Normal	Any	Any	Alive/Not Normal
	Abnormal High	Abnormal High	Fast	Any	Alive
	Abnormal High	Abnormal High	Non-Fast	Any	Alive/Not Normal
	Abnormal High	Abnormal Low	Any	Any	Alive/Not Normal
	Abnormal High	0	Any	Any	Alive/Not Normal
	Abnormal Low	Normal	Any	Any	Alive/Not Normal
	Abnormal Low	Abnormal	Any	Any	Alive/Not Normal
	Abnormal Low	0	Any	Any	Alive/Not Normal
	0	Normal	Any	Any	Alive/Not Normal
	0	Abnormal	Any	Any	Alive/Not Normal
	0	0	Any	Any	Dead
HR, RR, and Temp	Normal	Normal	Any	[redacted]	Alive
	Normal	Abnormal	Any	[redacted]	Alive/Not Normal
	Normal	0	Any	[redacted]	Alive/Not Normal
	Abnormal	Normal	Any	[redacted]	Alive/Not Normal
	Abnormal	Abnormal	Any	[redacted]	Alive/Not Normal
	Abnormal	0	Any	[redacted]	Alive/Not Normal
	0	Normal	Any	[redacted]	Alive/Not Normal
	0	Abnormal	Any	[redacted]	Alive/Not Normal
	0	0	Any	[redacted]	Dead
HR, Temp, and Acceleration	Normal	Normal	Any	Any	Alive
	Normal	H or L	Any	Any	Alive/Not Normal
	Abnormal High	Normal	Fast	Any	Alive
	Abnormal High	Normal	Non-Fast	Any	Alive/Not Normal
	Abnormal High	Abnormal	Any	Any	Alive/Not Normal
	Abnormal Low	Any	Any	Any	Alive/Not Normal
	0	Any	Any	Any	Dead
RR, Temp and Acceleration	Normal	Normal	Any	Any	Alive
	Normal	Abnormal	Any	Any	Alive/Not Normal
	Abnormal High	Normal	Fast	Any	Alive
	Abnormal High	Normal	Non-Fast	Any	Alive/Not Normal
	Abnormal High	Abnormal	Any	Any	Alive/Not Normal
	Abnormal Low	Any	Any	Any	Alive/Not Normal
	0	Any	Any	Any	[redacted]

*Note that the fourth value range is only filled in for acceleration (acceleration and orientation).

Table 11. Decision Matrix for Four Parameters Over the Last 16 Seconds

Parameters	Average Value Range 1	Average Value Range 2	Average Value Range 3	Average Value Range 4	Average Value Range 5	New State
HR, RR, Temp and Acceleration	Normal	Normal	Normal	Any	Any	Alive
	Normal	Normal	Abnormal	Any	Any	Alive
	Normal	Abnormal	Any	Any	Any	Alive/Not Normal
	Normal	0	Any	Any	Any	Alive/Not Normal
	Abnormal	Normal	*Any	Any	Any	Alive/Not Normal
	Abnormal High	Abnormal High	Any	Fast	Any	Alive
	Abnormal High	Abnormal High	Any	Non-Fast	Any	Alive/Not Normal
	Abnormal High	Normal	Any	Any	Any	Alive/Not Normal
	Abnormal High	Abnormal Low	Any	Any	Any	Alive/Not Normal
	Abnormal High	0	Any	Any	Any	Alive/Not Normal
	Abnormal Low	Normal	Any	Any	Any	Alive/Not Normal
	Abnormal Low	Abnormal	Any	Any	Any	Alive/Not Normal
	Abnormal Low	0	Any	Any	Any	Alive/Not Normal
	0	Normal	Any	Any	Any	Alive/Not Normal
	0	Abnormal	Any	Any	Any	Alive/Not Normal
	0	0	Any	Any	Any	Dead

*Note that the fifth value range is only filled in for acceleration (acceleration and orientation).

Red State Exceptions

These critical red states exceptions take priority over all other state decisions, regardless of the presence of other valid parameters:

- If HR = 0 for 4 minutes or more, New state = RED, and Confidence Score = 100
- HR <30 BPM for 10 minutes or more, New state = RED, and Confidence Score = 100
- RR = 0 for 5minutes or more, New state = RED, and Confidence Score = 100

Confidence Score

There are three components to the confidence score:

- **State change score** – This score reflects the likelihood of the observed state change
- **State persistence score** – The number of times the new state was previously observed in sequence
- **Parameter set weight** - A multiplier intended to reflect the breadth of the most recent set of available parameters

State Change Score

State change score is a reflection of the likelihood of going from one health state to another. The underlying probabilities are based on the following assumptions:

- Vital signs activity tends to stabilize after a sustained period in a given level of activity for normal healthy adults
- The sensor platform captures data quickly enough to expect health state changes to typically occur in no more than one step at a time
- State changes of two or more steps are likely to reflect critical wounding. In the absence of actual data for likelihood of a soldier being wounded, a rough estimate was used to determine that probability

Table 12 describes the components of the state change score.

Table 12: State Change Score Components

# of State Change Steps	Variations	Total Probability	State Change Score	Influence on Conf Score
0	GG, YY, RR	60%	3	H
1	RHYH, YHG, GYL, YLRL	30%	2	M
2 or More	GRH, GRL	10%	1	L

State Persistence Score

The confidence score factors in the amount of time that the health state does not change. As stated earlier, vital signs activity tends to stabilize after a sustained period in a given level of activity for normal healthy adults. Therefore, the algorithm assumes that persistence of a green, red, or yellow state improves the likelihood that the sensor data and resulting health state assessment are correct.

Persistence reflects at most 16 seconds of data (8 data samples), so the maximum value is 7, and minimum value is 0. Table 14 relates the persistence score to High Low and Medium influence of state persistence on the overall confidence score.

Table 13 describes the component of the persistence score.

Table 13. Persistence Score Components

Total # Times In New State	Score Range (Total –1)	Influence on Conf Score
7 - 8	6 - 7	H
5 - 6	4 - 5	M
4	3	L

Parameter Set Weight

The parameter set weight is an indicator of the number and importance of the parameters used to make the health state assessment.

Table 14 describes the components of the parameter set weight.

Table 14. Components of Weight (Multiplier) by Parameter Set

Parameter Included in New State	Weight (Multiplier)	Influence on Conf Score
All	1.0	H
HR, RR, and Motion		
HR, RR, Temp	0.9	M
HR and RR		
HR and Temp	0.8	L
HR and Motion		
HR		
RR and Temp		
RR and Motion		
RR		

Confidence Score Calculation

The confidence score is a value of 10 or less rounded to one decimal place, with 10 as the highest possible confidence score. See Table 15 below for value ranges. Calculate the score as follows:

Confidence score = parameter set weight * (state change score + persistence score)

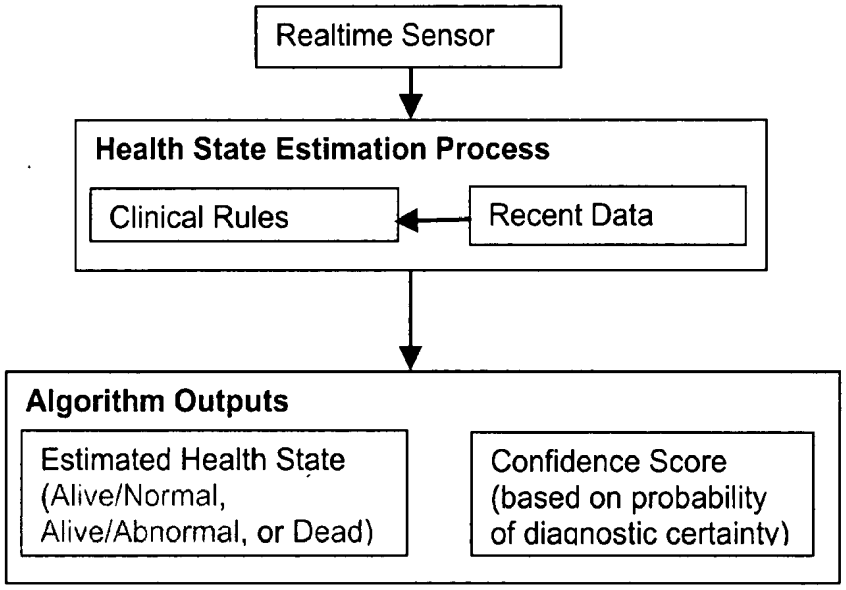
Table 15. Confidence Score Ranges

Confidence Level	Score Range
High	8<Score10
Medium	5< Score8
Low	Score <5

Health State Assessment Algorithm: Overview of Functional Flow

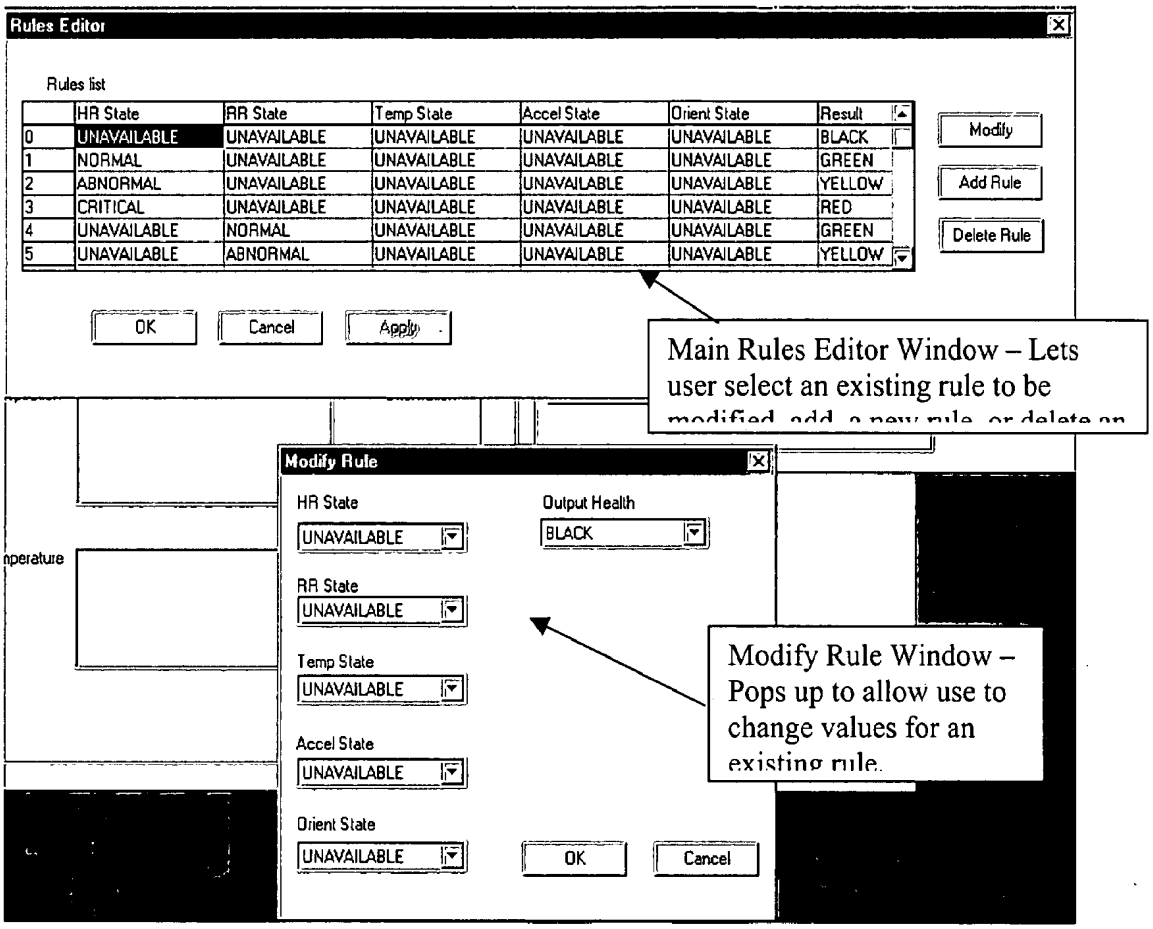
I. Basic Functional Flow Diagram

The health state assessment algorithm (HSAA) provides a flexible, automated process for remotely assessing an individual's health status based on realtime monitoring of vital signs and other contextual life signs. The process is design to be implemented in firmware as well as in interactive, graphical software. The design specifies (1) the basic functional process for determining health state from realtime monitoring results, (2) a multi-tier approach foroperation of the algorithm process in different usage situations and on computing platforms with different processing capabilities, (3) a set of tools to optimize the usefulness depending on usage platform, and (4) a set of customization tools for setting up clinical rules sets for various remote monitors (variable sensor arrays).



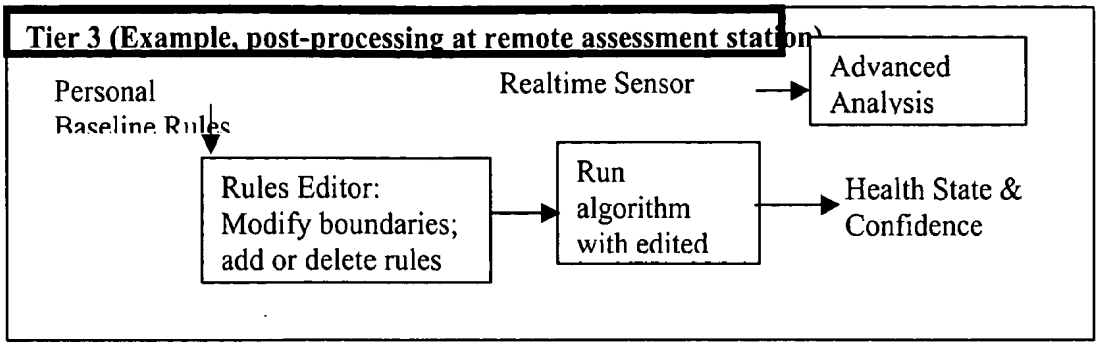
II. Multi-Tier Design Details

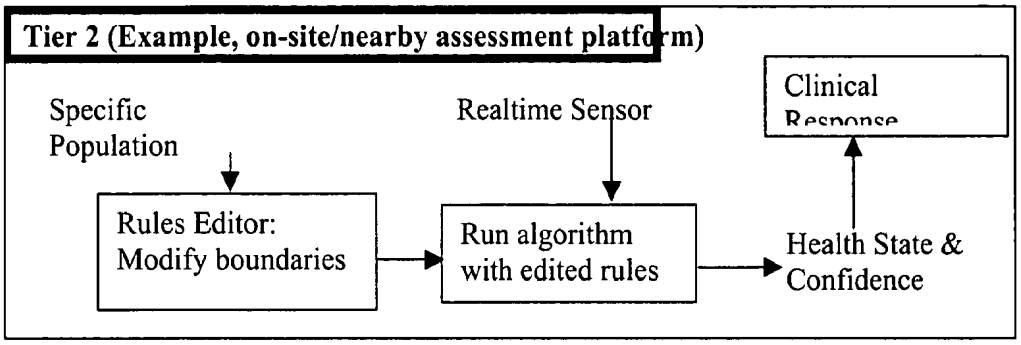
A. The Rules Editor – Allows end users (clinicians, medics, for example) to modify the rules boundaries for numeric values and change the value set for literal values. It also allows technical users to add or delete clinical rules.

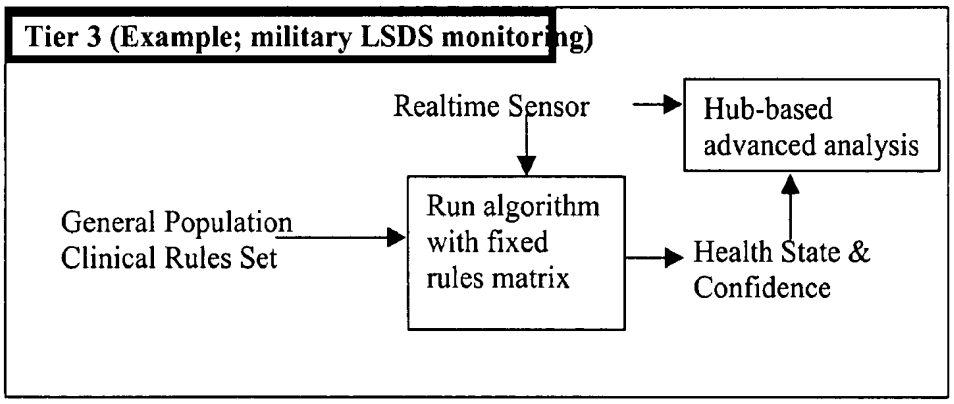


B. Optional Rules Set – Allows implementers to select the base rules set for processing the outputs of the sensor: generalized population rules (e.g., adult males), specified population rules (e.g., healthy males, 18 to 21 years old), personal baseline (e.g., John Smith before being deployed into combat environment).

C. Functional Flow by Tier


Tier 3 (Example, post-processing at remote assessment station)
Personal
Baseline Rules
Realtime Sensor
Advanced
Analysis
Rules Editor:
Modify boundaries;
add or delete rules
Run
algorithm
with edited
Health State &
Confidence


Tier 2 (Example, on-site/nearby assessment platform)
Specific
Population
Realtime Sensor
Clinical
Response
Rules Editor:
Modify boundaries
Run algorithm
with edited rules
Health State &
Confidence


Tier 3 (Example; military LSDS monitoring)
Realtime Sensor
Hub-based
advanced analysis
General Population
Clinical Rules Set
Run algorithm
with fixed
rules matrix
Health State &
Confidence

Abstract

A wearable platform embodied in a belt or patch provides physiological monitoring of soldiers during field operations or trauma victims at accident sites and makes health state assessments. The platform includes sensors for heart rate, body motion, respiration rate and intensity, and temperature and further contains a microprocessor and short range transmitter. The respiration sensor uses conductive ink in a novel manner. A small square of the ink is coated on an arched structure so that flexing of the arch either to increase or decrease its radius of curvature modifies the resistance of the structure. This is utilized to set the unstressed resistance of the arch structure and to allow a greater range of resistance values capable of measuring distortions in different deformations of the arch. The respiration sensor supplements the motion information provided by an accelerometer sensor. The heart rate sensor employs skin contact electrodes and a high impedance amplifier to generate an electrical EKG signal. An analog circuit running a novel algorithm obtains the R-wave period from the EKG signal and produces electrical pulses with the period between pulses corresponding to the R-wave period. An evaluation algorithm makes a medical evaluation of subject condition and determines a confidence level for the evaluation. The information is communicated wirelessly to a local hub for relay to a remote monitor.

Fig. 1

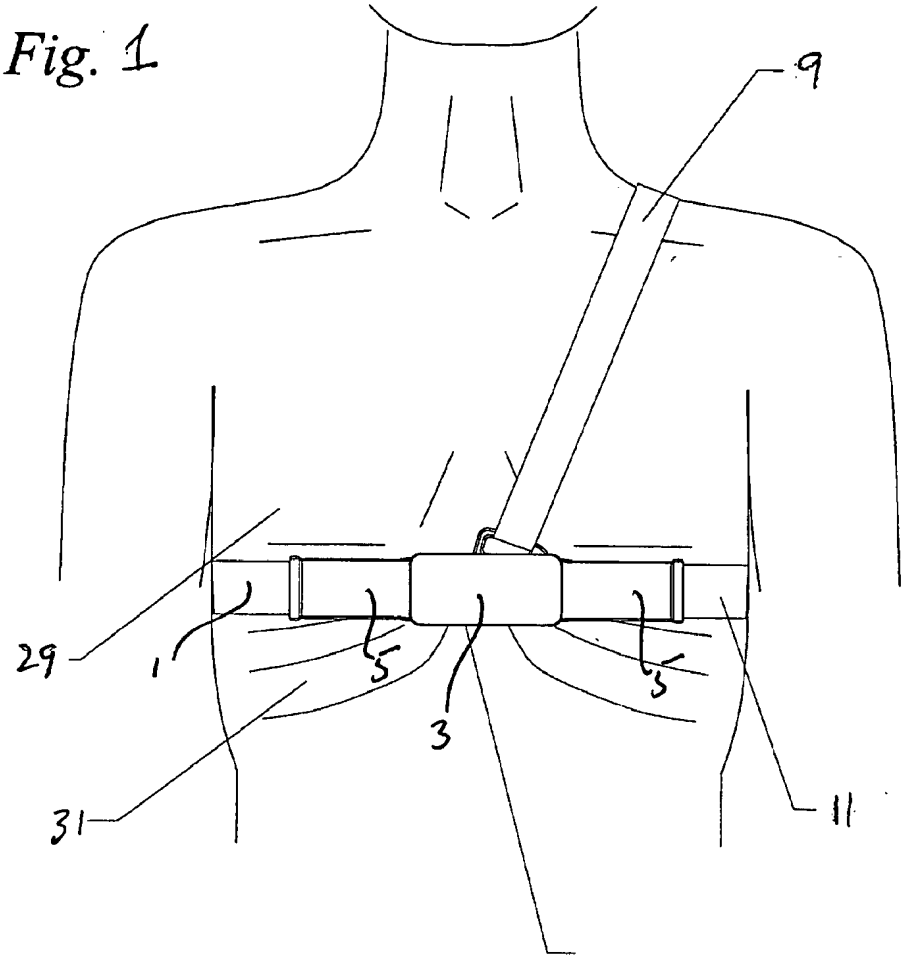


Fig. 3

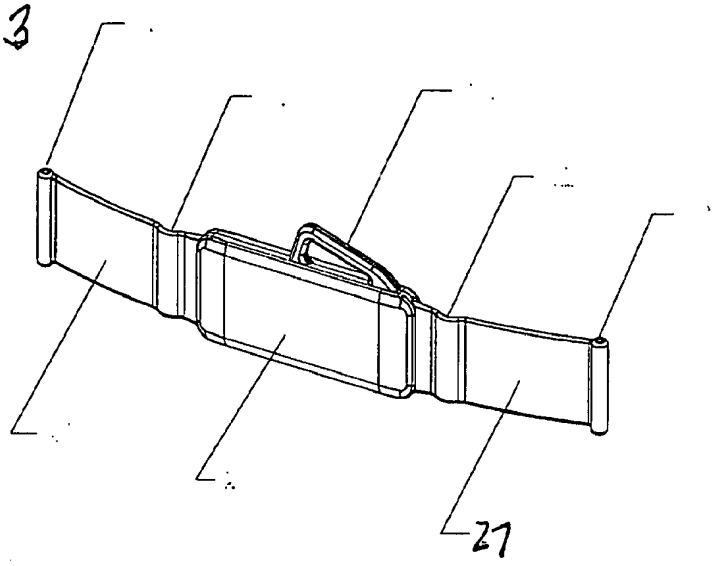


Fig. 2

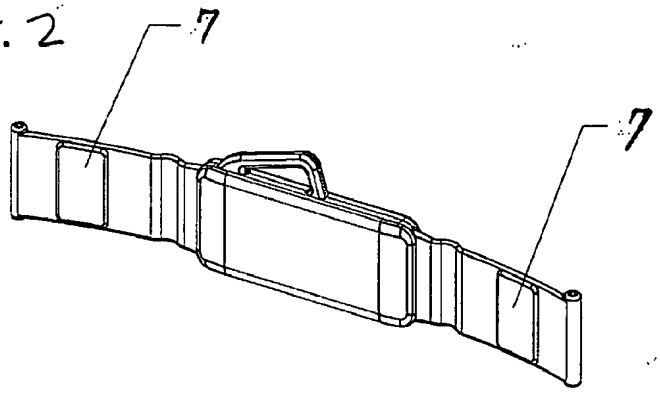


Fig. 4

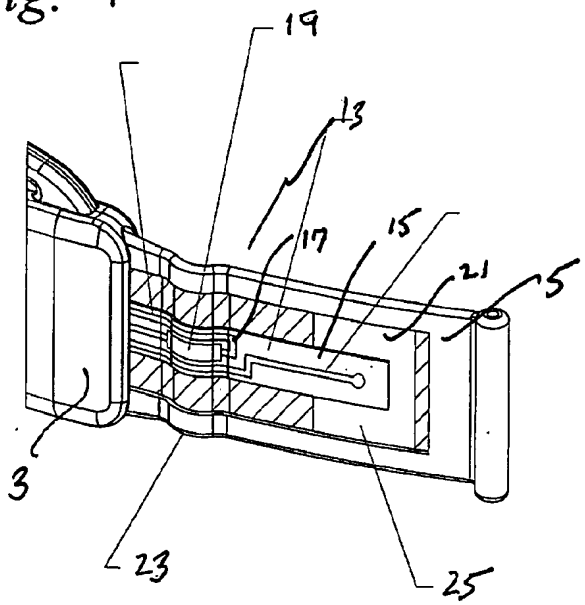


Fig. 5

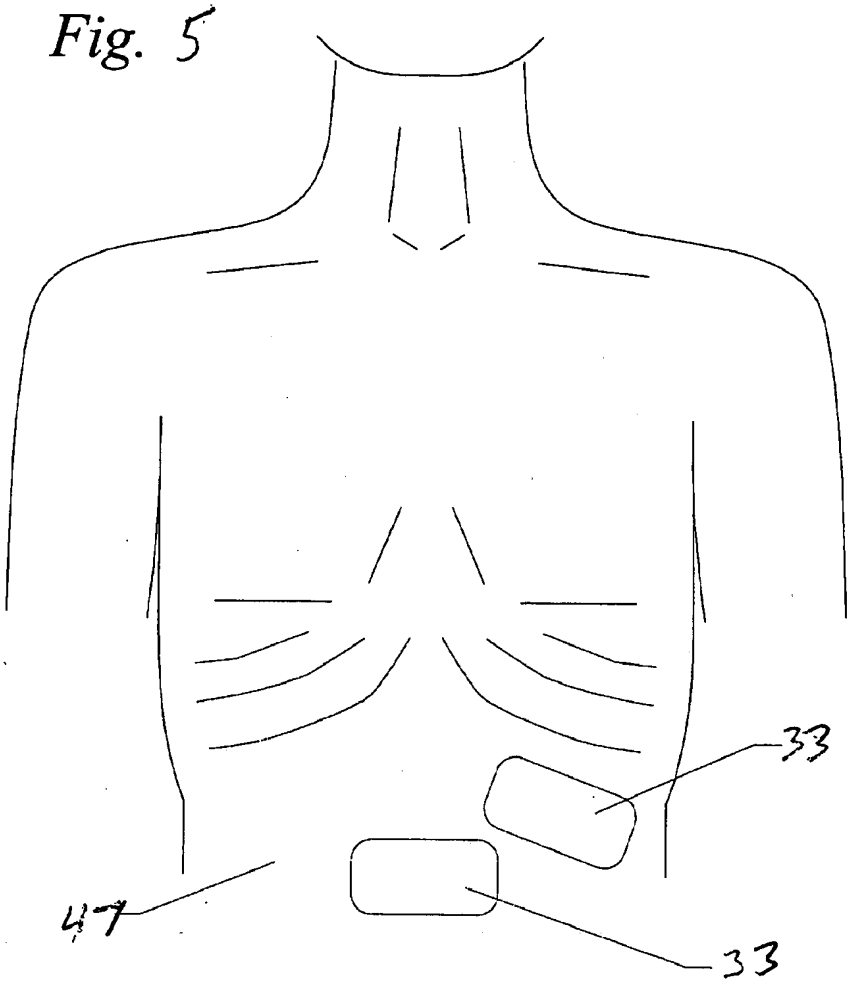


Fig. 6

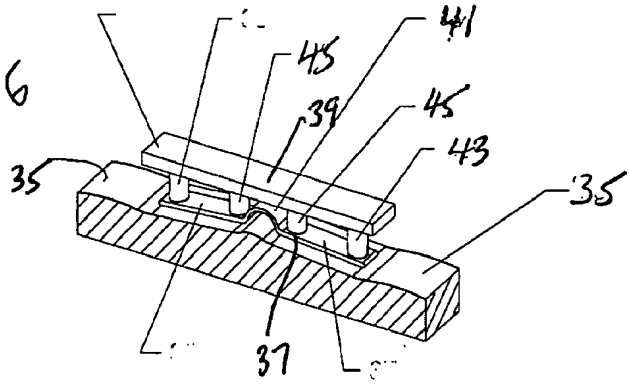


Fig. 7

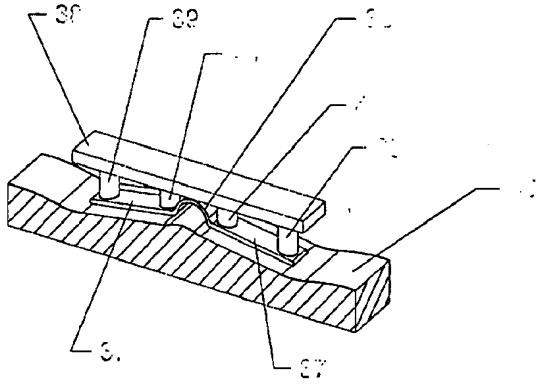


Fig. 8

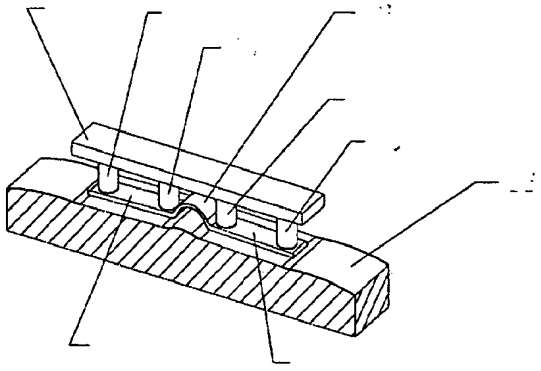


Fig. 9

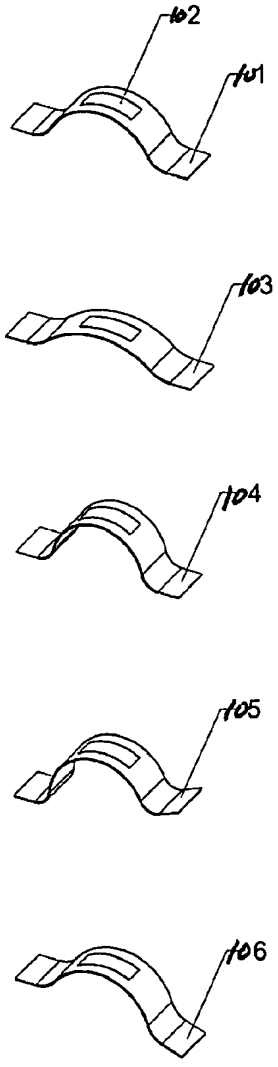


Fig. 10

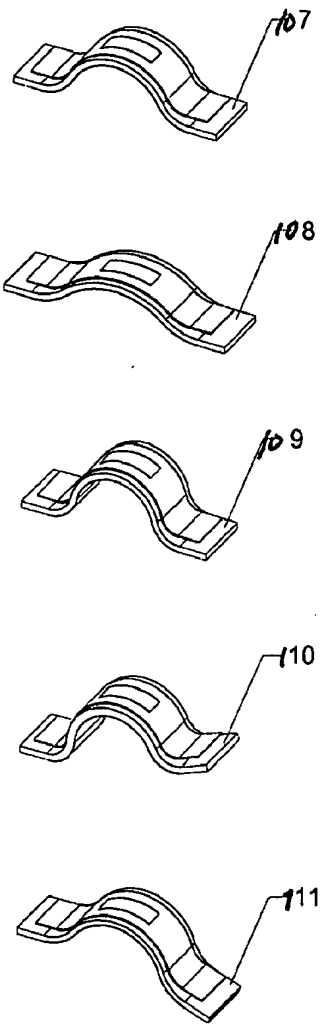


Fig. 11

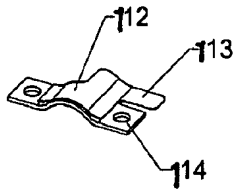
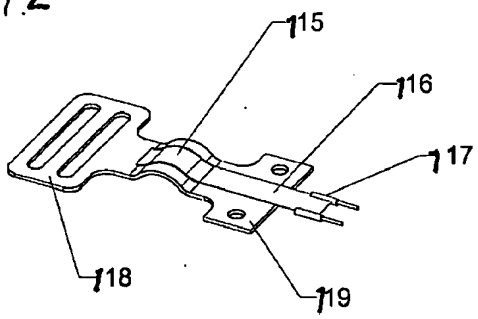


Fig. 12



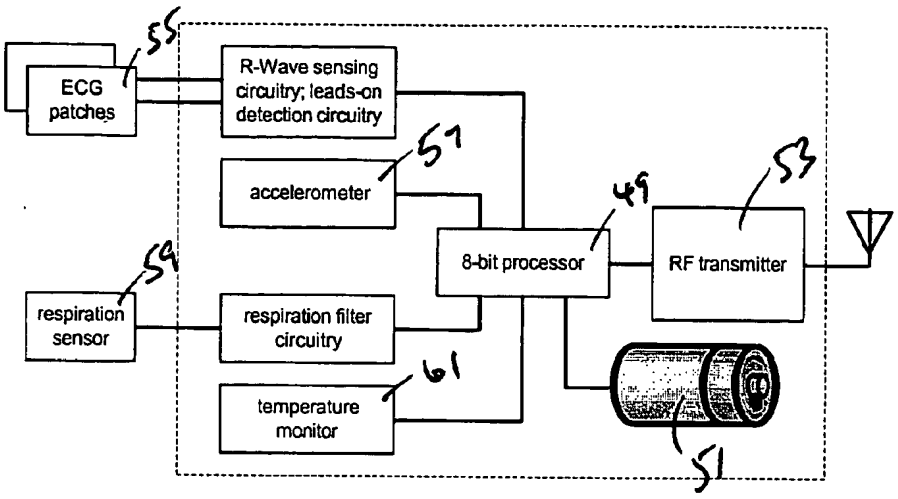

ECG patches
55
R-Wave sensing circuitry; leads-on detection circuitry
accelerometer
57
8-bit processor
49
RF transmitter
53
respiration sensor
59
respiration filter circuitry
temperature monitor
61
51

Fig. 13

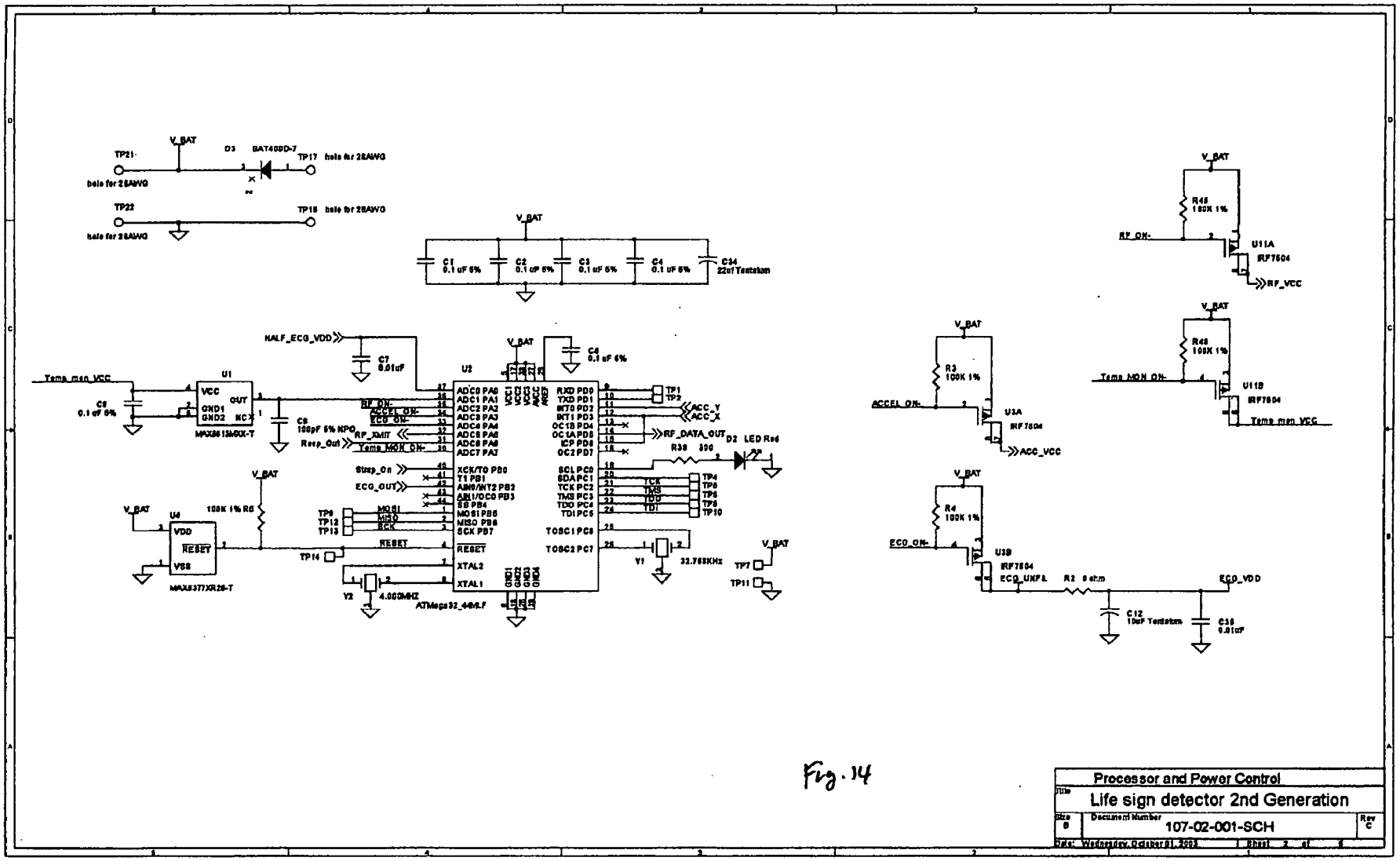


Fig. 14

Title	Processor and Power Control	
	Life sign detector 2nd Generation	
Size: B	Document Number: 107-02-001-SCH	Rev: C
Date: Wednesday, October 01, 2003	Sheet 2 of 6	

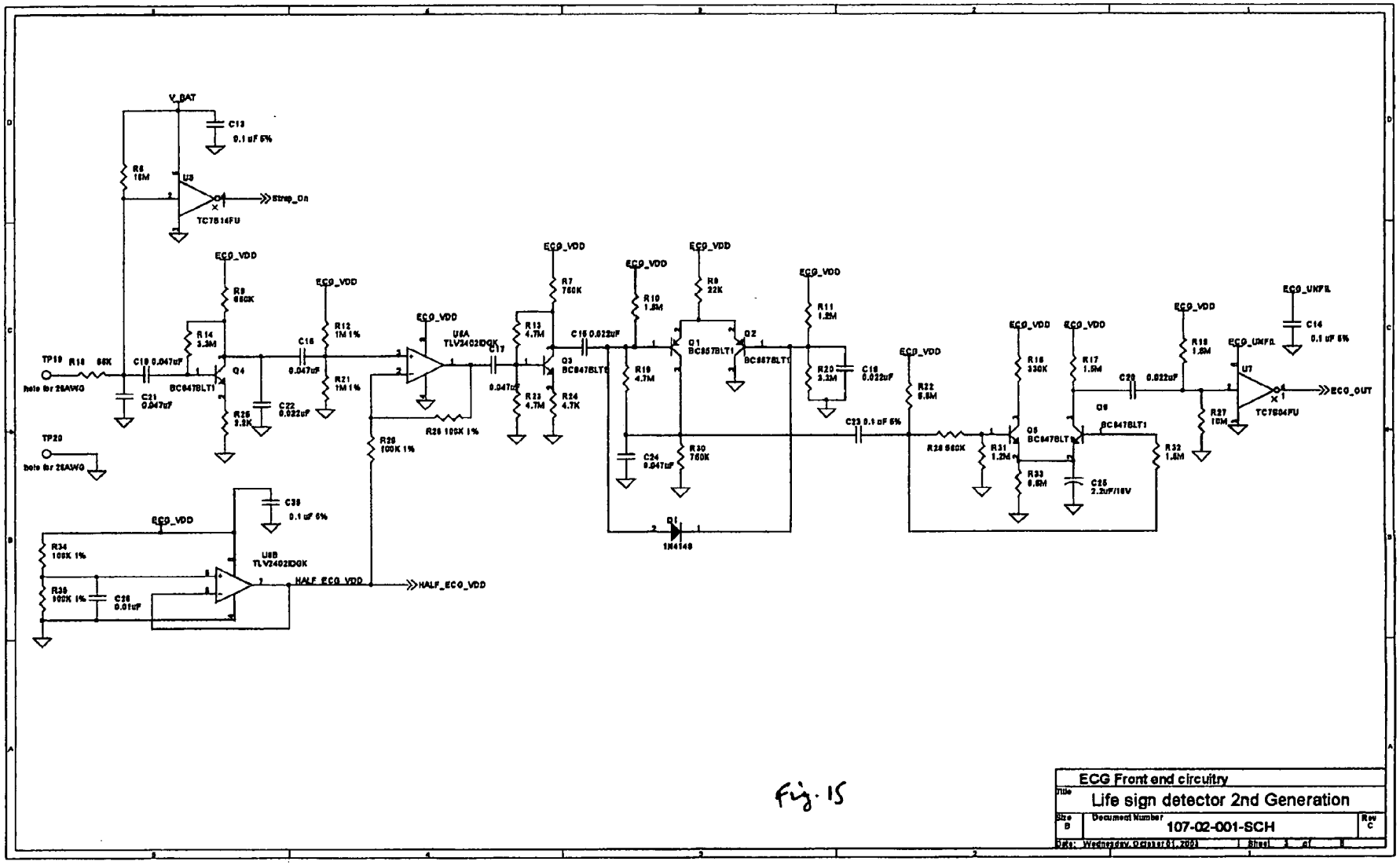


Fig. 15

Title	ECG Front end circuitry	
	Life sign detector 2nd Generation	
Size B	Document Number 107-02-001-SCH	Rev C
Date: Wednesday, October 01, 2003	Sheet 1 of 1	

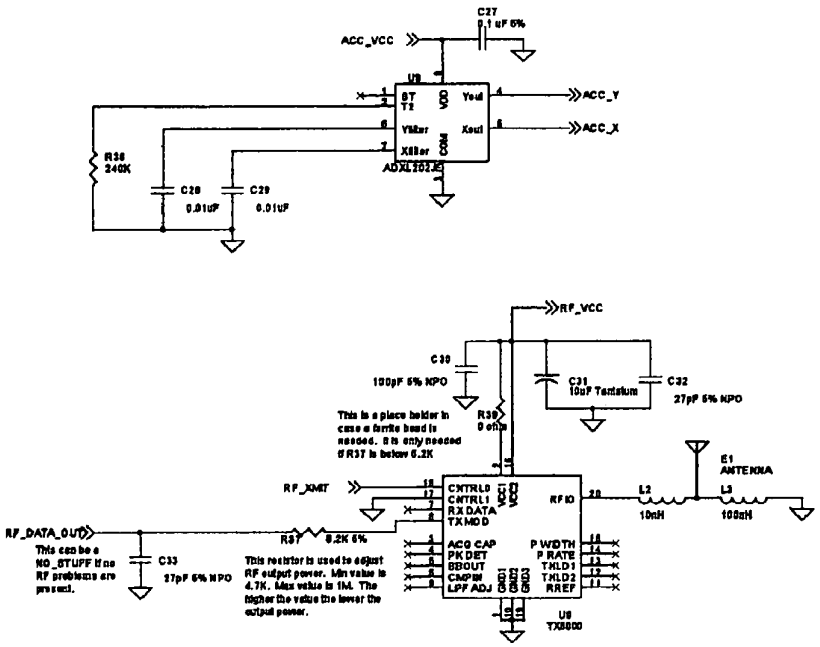


Fig 16

Accelerometer and Rf Circuit		
Title: Life sign detector 2nd Generation		
Size: B	Document Number: 107-02-001-SCH	Rev: C
Date: Wednesday, October 01, 2003	Sheet 4 of 8	

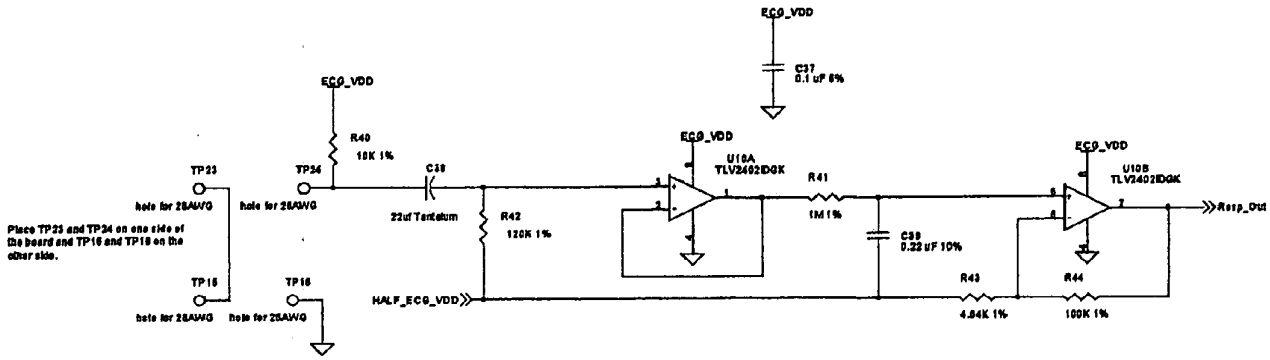


Fig 17

Title	Respiration circuitry.	
	Life sign detector 2nd Generation	
Size B	Document Number 107-02-001-SCH	Rev C
Date: Wednesday, October 01, 2003	Sheet 8 of 8	

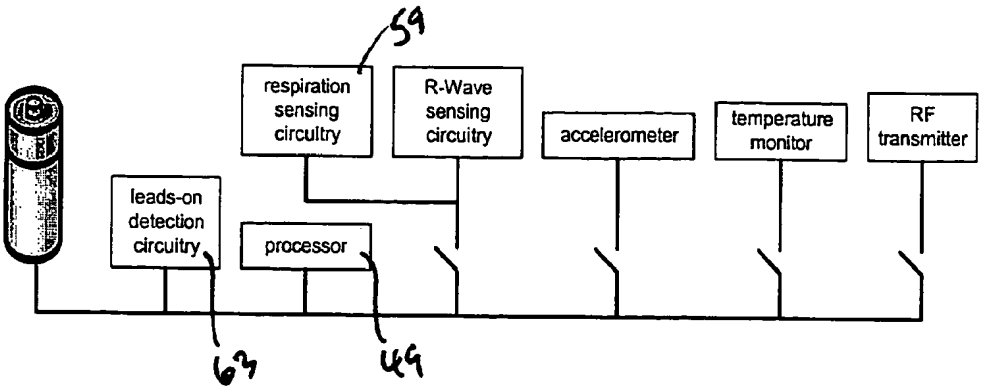

59
respiration sensing circuitry
R-Wave sensing circuitry
accelerometer
temperature monitor
RF transmitter
leads-on detection circuitry
processor
63
49

Fig. 18

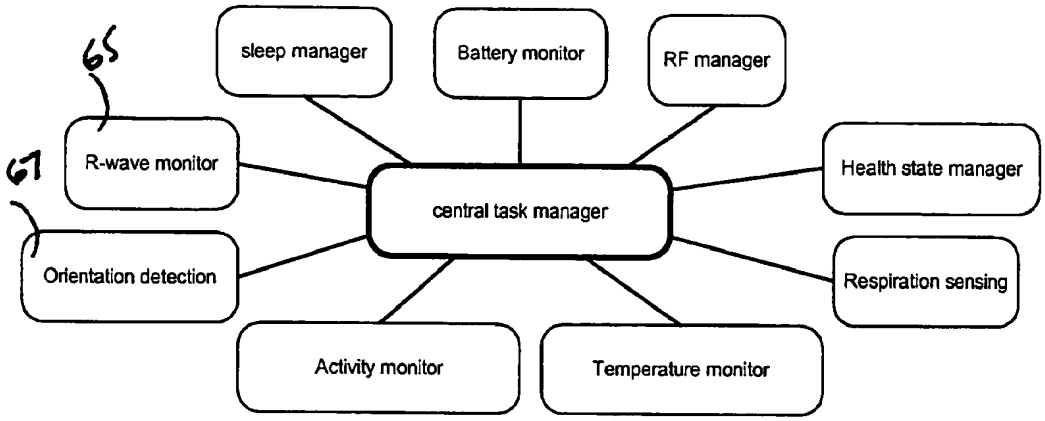

65
67
sleep manager
Battery monitor
RF manager
R-wave monitor
Health state manager
central task manager
Orientation detection
Respiration sensing
Activity monitor
Temperature monitor

Fig. 19

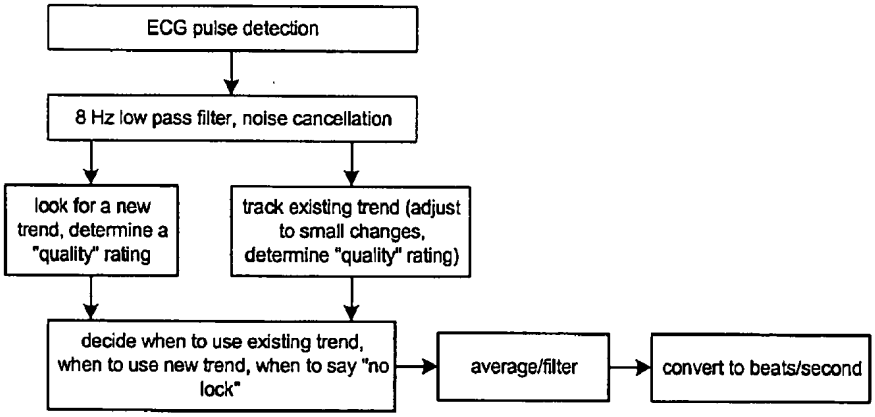

ECG pulse detection
8 Hz low pass filter, noise cancellation
look for a new trend, determine a "quality" rating
track existing trend (adjust to small changes, determine "quality" rating)
decide when to use existing trend, when to use new trend, when to say "no lock"
average/filter
convert to beats/second

Fig. 20

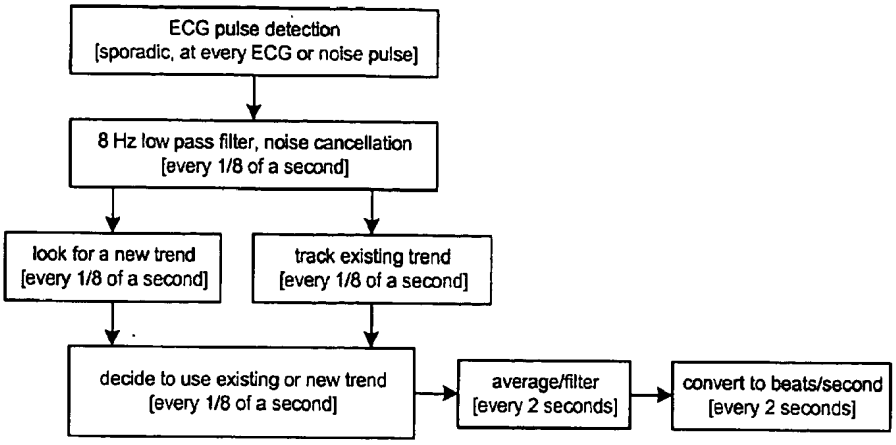

ECG pulse detection
[sporadic, at every ECG or noise pulse]
8 Hz low pass filter, noise cancellation
[every 1/8 of a second]
look for a new trend
[every 1/8 of a second]
track existing trend
[every 1/8 of a second]
decide to use existing or new trend
[every 1/8 of a second]
average/filter
[every 2 seconds]
convert to beats/second
[every 2 seconds]

Fig. 21

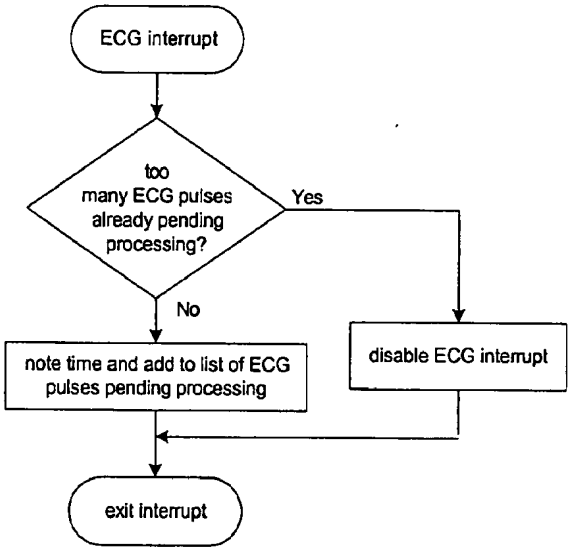

ECG interrupt
too
many ECG pulses
already pending
processing?
Yes
No
note time and add to list of ECG
pulses pending processing
disable ECG interrupt
exit interrupt

Fig. 22

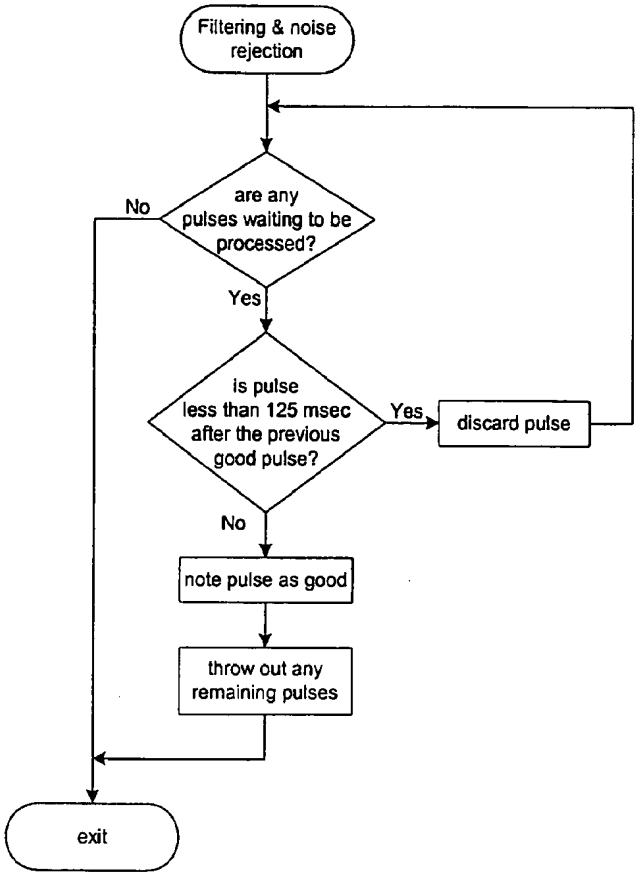

Filtering & noise rejection
are any pulses waiting to be processed?
No
Yes
is pulse less than 125 msec after the previous good pulse?
Yes
discard pulse
No
note pulse as good
throw out any remaining pulses
exit

Fig. 23

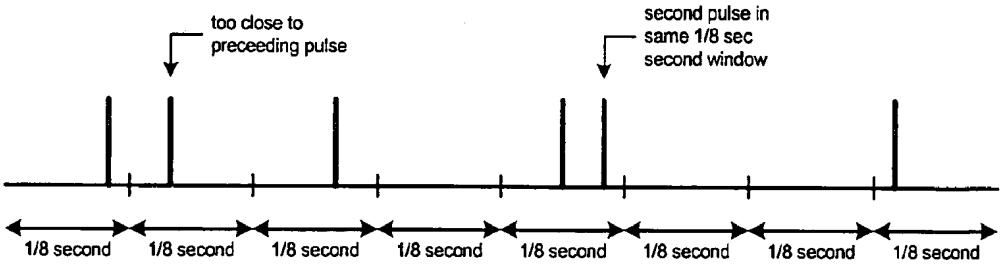

too close to preceeding pulse
second pulse in same 1/8 sec second window
1/8 second
1/8 second
1/8 second
1/8 second
1/8 second
1/8 second
1/8 second
1/8 second

Fig. 24

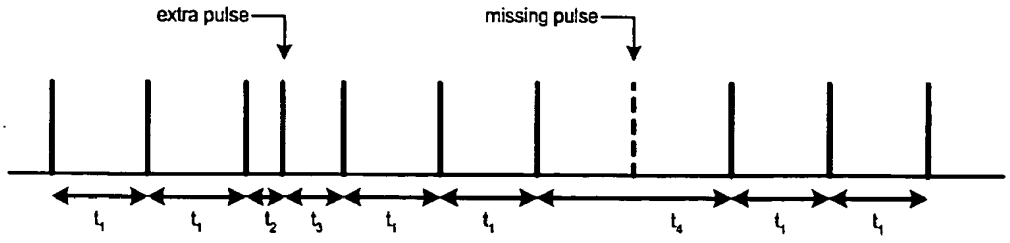

extra pulse
missing pulse
t1
t1
t2
t3
t1
t1
t4
t1
t1

Fig. 25

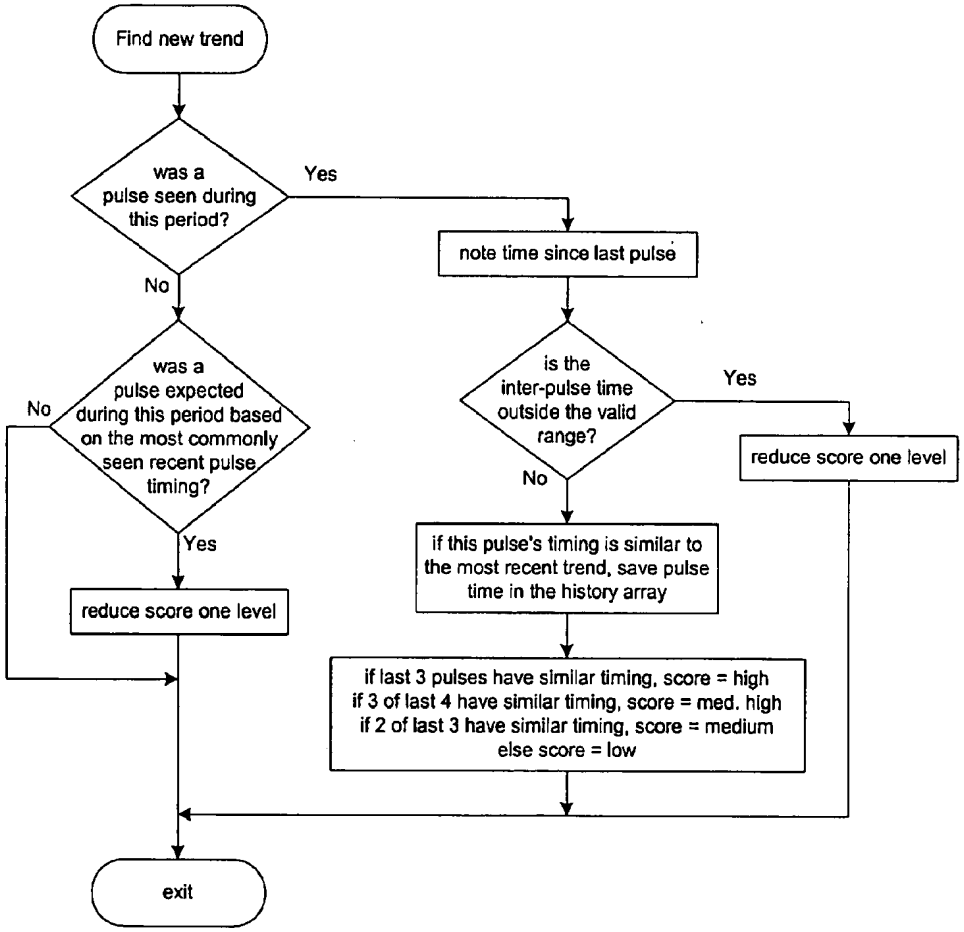

Find new trend
was a pulse seen during this period?
Yes
No
note time since last pulse
was a pulse expected during this period based on the most commonly seen recent pulse timing?
No
Yes
is the inter-pulse time outside the valid range?
Yes
No
reduce score one level
reduce score one level
if this pulse's timing is similar to the most recent trend, save pulse time in the history array
if last 3 pulses have similar timing, score = high
if 3 of last 4 have similar timing, score = med. high
if 2 of last 3 have similar timing, score = medium
else score = low
exit

Fig. 26

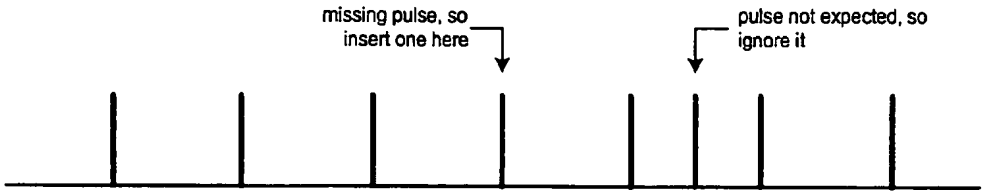

missing pulse, so insert one here
pulse not expected, so ignore it

Fig. 27

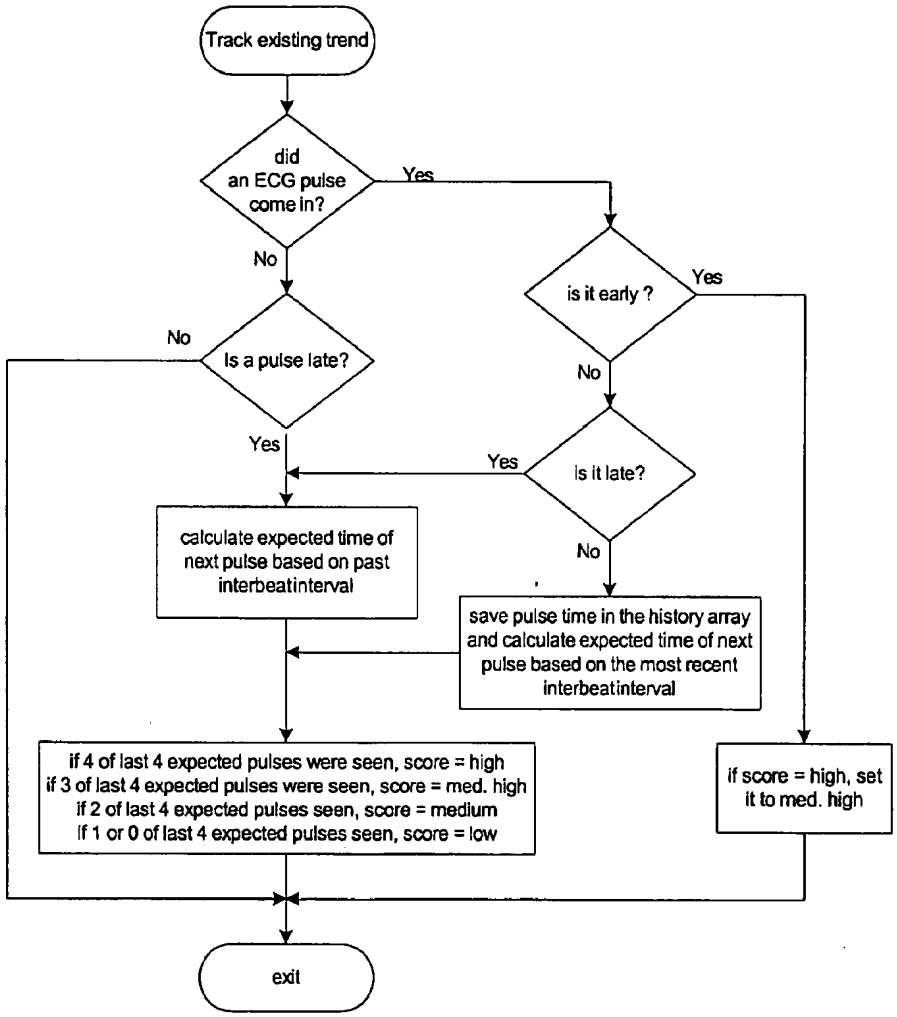

Track existing trend
did an ECG pulse come in?
Yes
No
is it early ?
Yes
No
Is a pulse late?
No
Yes
Yes
Is it late?
No
calculate expected time of next pulse based on past interbeatinterval
save pulse time in the history array and calculate expected time of next pulse based on the most recent interbeatinterval
if 4 of last 4 expected pulses were seen, score = high
if 3 of last 4 expected pulses were seen, score = med. high
if 2 of last 4 expected pulses seen, score = medium
If 1 or 0 of last 4 expected pulses seen, score = low
if score = high, set it to med. high
exit

Fig. 28

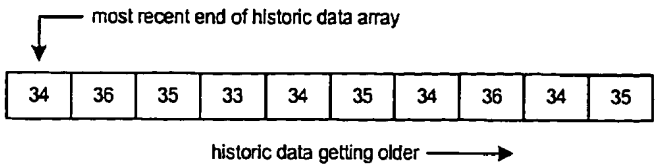


Fig. 29

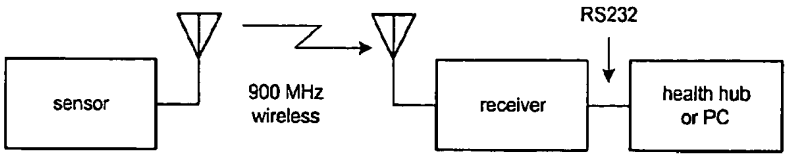


Fig. 30

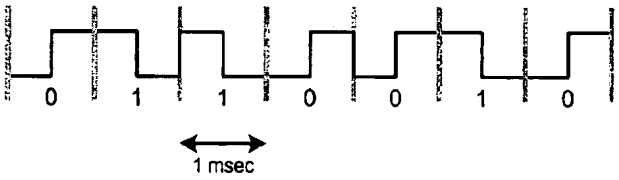


Fig. 31

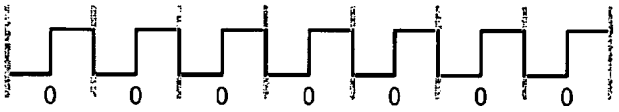


Fig. 32

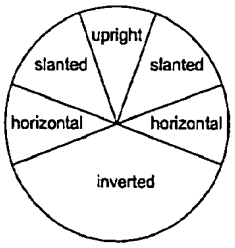


Fig. 33